

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states

Alendronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	AB-Consult Handels- und Betriebsberatungs GmbH, Eichenstraße 32, A-1120 Wien, Austria	Alemol 70 mg - einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	AB-Consult Handels- und Betriebsberatungs GmbH, Eichenstraße 32, A-1120 Wien, Austria	Alenat 70 mg - einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Hexal Pharma GmbH, Stella- Klein-Löw-Weg 17, A-1020 Wien, Austria	Alendrohexal 70 mg - einmal wöchentlich Filmtabletten	70 mg	film-coated tablet	Oral Use
AT - Austria	Genericon Pharma GmbH, Hafnerstraße 211, A-8054 Graz, Austria	Alendronorm 70 mg - einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Accord Healthcare Ltd, Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, UK	Alendronsäure Accord 70 mg einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Accord Healthcare Ltd, Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, UK	Alendronsäure Accord 10 mg Tabletten	10 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Actavis Group PTC ehf, Reykjavikurvegur 76-78, 220 Hafnarfjörður, Iceland	Alendronsäure Actavis 70 mg einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Arcana Arzneimittel GmbH, Hütteldorfer Straße 299, A-1140 Wien, Austria	Alendronsäure 'Arcana' 70 mg - einmal wöchentlich - Tabletten	70 mg	tablet	Oral Use
AT - Austria	Bluefish Pharmaceuticals AB, Torsgatan 11, 111 23 Stockholm, Sweden	Alendronsäure Bluefish 70 mg einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Interpharm Produktions GmbH, Effingergasse 21, A- 1160 Wien, Austria	Alendronsäure 'Interpharm' 70 mg einmal wöchentlich - Tabletten	70 mg	tablet	Oral Use
AT - Austria	Interpharm Produktions GmbH, Effingergasse 21, A- 1160 Wien, Austria	Alendronsäure 'Interpharm' 10 mg - Tabletten	10 mg	tablet	Oral Use
AT - Austria	1A Pharma GmbH, Stella- Klein-Löw-Weg 17, A-1020 Wien, Austria	Alendronsäure 1A Pharma 70 mg - einmal wöchentlich Filmtabletten	70 mg	film-coated tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert-Schweitzer Gasse 3 A-1140 Wien Austria	Alendronsäure 'ratiopharm' 70 mg - einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Sandoz GmbH, Biochemiestraße 10 A-6250 Kundl, Austria	Alendronsäure Sandoz 70 mg - einmal wöchentlich Filmtabletten	70 mg	film-coated tablet	Oral Use
AT - Austria	Stada Arzneimittel GmbH Muthgasse 36 A-1190 Wien Austria	Alendronstad 70 mg einmal wöchentlich Tabletten	70 mg	tablet	Oral Use
AT - Austria	Merck Sharp & Dohme GmbH, EURO PLAZA Gebäude G, 5.Stock, Am Euro Platz 2, A-1120 Wien, Austria	Fosamax einmal wöchentlich 70 mg Tabletten	70 mg	tablet	Oral Use
AT - Austria	Merck Sharp & Dohme GmbH, EURO PLAZA Gebäude G, 5.Stock, Am Euro Platz 2, A-1120 Wien, Austria	Fosamax 10 mg - Tabletten	10 mg	tablet	Oral Use
BE - Belgium	Arrow Generics Limited 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Alendronate Arrow Generics	10 mg	Tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Arrow Generics Limited 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Alendronate Arrow Generics	70 mg	Tablets	Oral Use
BE - Belgium	Eurogenerics N.V. Heizel Esplanade b22 1020 Brussels Belgium	Alendronate EG	10 mg	Tablets	Oral Use
BE - Belgium	Eurogenerics N.V. Heizel Esplanade b22 1020 Brussels Belgium	Alendronate EG	70 mg	Tablets	Oral Use
BE - Belgium	Mylan BVBA/SPRL Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Alendronate Mylan	10 mg	Tablets	Oral Use
BE - Belgium	Mylan BVBA/SPRL Terhulpsesteenweg 6A 1560 Hoeilaart Belgium	Alendronate Mylan	70 mg	Tablets	Oral Use
BE - Belgium	Teva Pharma Belgium N.V. Laarstraat 16 2610 Wilrijk Belgium	Alendronate teva	70 mg	Tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Merck Sharp & Dohme B.V. Clos du Lynx, 5- 1200 Brussels, Belgium	Fosamax hebdomadaire	70 mg	Tablets	Oral Use
BE - Belgium	Merck Sharp & Dohme B.V. Clos du Lynx, 5- 1200 Brussels, Belgium	Fosamax	10 mg	Tablets	Oral Use
BG - Bulgaria	Tchaikapharma 1172 Sofia 1 G. M. Dimitrov Blvd Sofia Bulgaria	Fosanate	70 mg	film-coated tablets	Oral Use
BG - Bulgaria	Betapharm Arzneimittel GmbH, Kobelweg 95, 86156 Augsburg , Germany	Instrel	70 mg	tablets	Oral Use
BG - Bulgaria	Smarjeska cesta 6, 8501 Novo mesto – Slovenia	Lindron	10 mg	tablets	Oral Use
BG - Bulgaria	Teva Pharmaceuticals N.V.Gogol 15 ЕООД Sofia Bulgaria	Tevanate	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BG - Bulgaria	Actavis Group PTC ehf, Iceland Reykjavikurvegur 76-78, IS-220, Hafnarfjordur	Alendronat Actavis	70 mg	tablets	Oral Use
BG - Bulgaria	Sandoz GmbH, 10 Biochemie strasse, A-6250 Kundl, Austria	Forosa	70 mg	film - coated tablets	Oral Use
BG - Bulgaria	Merck Sharp & Dohme Bulgaria 55, Nicola Vaptzarov blvd. EXPO 2000 1st floor-east wing, sections B1&B2 Sofia 1407 Bulgaria.	Fosamax OW	70 mg	tablets	Oral Use
CY - Cyprus	Merck Sharp & Dohme BV, Waarderweg 39, 2031 bn Haarlem, The Netherlands	Fosamax tablet 70mg	70mg	tablets	Oral Use
CY - Cyprus	Pharmanel Pharmaceuticals SA, 106 Marathons Avenue, Athens, Greece	Difonate tablet 70mg	70mg	tablets	Oral Use
CY - Cyprus	Farmanic-Chemipharma SA, 137 Filis Avenue, 13451 Kamatero, Attikis, Greece	Ledronin tablet 70mg	70mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CY - Cyprus	Arrow Generics Limited, Unit 2 Eastman Way,Hertfordshire, SG1 4SZ,Stevenage,UK	Alendronic -Acid Arrow tablet 10mg	10mg	tablets	Oral Use
CY - Cyprus	Arrow Generics Limited, Unit 2 Eastman Way,Hertfordshire, SG1 4SZ,Stevenage,UK	Alendronic -Acid Arrow tablet 70mg	70mg	tablets	Oral Use
CY - Cyprus	Aurobindo Pharma (Malta) Limited, 46/2 South street, Valetta, Malta	Alendronic Acid Aurobindo tablet 70mg	70mg	tablets	Oral Use
CZ - Czech Republic	Orion Corporation, Orionintie 1A, FI-02200 Espoo, Finland	Aldrion 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Generics Ltd., Mylan Albany Gate, Darkes Lane, Potters Bar Hertfordshire EN6 1AG United Kingdom	Alendrogen 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Actavis Group hf. Reykavikurvegi 76-78 220 Hafnarfirdi Iceland	Alendronat Actavis 70mg	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Accord Healthcare Ltd Sage House Pinner Road Harrow Middlesex HA1 4HF United Kingdom	Alendronát Natrium Accord 10mg	10mg	Tablet	Oral Use
CZ - Czech Republic	Accord Healthcare Ltd Sage House Pinner Road Harrow Middlesex HA1 4HF United Kingdom	Alendronát Natrium Accord 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Sandoz GmbH, Biochemiestraße 10 6250 Kundl, Austria	Alendronat Sandoz 70	70mg	Tablet	Oral Use
CZ - Czech Republic	Ratiopharm GmbH, Graf- Arco-Straße 3 89079 Ulm, Germany	Alendronat- Ratiopharm 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Teva Pharmaceuticals CR, s.r.o., Radlická 3185/1c 150 00 Praha 5 Czech Republic	Alendronate_Teva 70mg	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Arrow Generics Ltd 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Alenwin 70	70mg	Tablet	Oral Use
CZ - Czech Republic	Apotex Nederland BV Bio Science Park Archimedesweg 2 2333 CN Leiden, Netherlands	Apo-Alendronat 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Merck Sharp & Dohme BV Waarderweg 39, 2031 BN Haarlem, Netherlands	Fosamax 70mg 1xtýdně	70mg	Tablet	Oral Use
CZ - Czech Republic	Arrow Generics Ltd 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Fosteofos 70	70mg	Tablet	Oral Use
CZ - Czech Republic	Bentley Pharmaceuticals Ireland Ltd, 25/28 North Wall Quay, Dublin 1, Ireland	Gendron 70mg	70mg	Tablet	Oral Use
CZ - Czech Republic	Richter Gedeon Nyrt. Gyömrői út 19-21. H-1103 Budapest Hungary	Siranin 70mg potahované tablety	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevanate 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevanate 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevabone-4 70 mg Tabletten und 1 Mikrogramm Weichkapseln	70 mg 1 µ	Tablet and Capsule soft	Oral Use
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevabone-5 70 mg Tabletten und 1 Mikrogramm Weichkapseln	70 mg 1 µ	Tablet and Capsule soft	Oral Use
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevabone-3 70 mg Tabletten und 1 Mikrogramm Weichkapseln	70 mg 1 µ	Tablet and Capsule soft	Oral Use
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevabone-2 70 mg Tabletten und 1 Mikrogramm Weichkapseln	70 mg 1 µ	Tablet and Capsule soft	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Tevabone 70 mg Tabletten und 1 Mikrogramm Weichkapseln	70 mg 1 µ	Tablet and Capsule soft	Oral Use
DE - Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching	Alendronsäure - 1 A Pharma 70 mg Filmtabletten	70 mg	Film-coated tablet	Oral Use
DE - Germany	AbZ-Pharma GmbH Dr.Georg-Spohn-Str. 7 D-89143 Blaubeuren	Alendronsäure AbZ 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Accord Healthcare Limited Sage House, 319, Pinner Road GB-HA1 4HF NORTH HARROW, MIDDLESEX	Alendronsäure Accord 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Accord Healthcare Limited Sage House, 319, Pinner Road GB-HA1 4HF NORTH HARROW, MIDDLESEX	Alendronsäure Accord 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	acis Arzneimittel GmbH Lil-Dagover-Ring 7 D-82031 Grünwald	Alendronat acis 70 mg Tabletten	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Actavis Group PTC ehf Reykjavikurvegur 76 - 78 IS-220 Hafnarfjörður	Alendronsäure-Actavis 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Alendronsäure AL 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul	Alendronsäure AWD 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul	Alendronsäure AWD 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	axcount Generika AG Max-Planck-Str. 36b D-61381 Friedrichsdorf	Alendronsäure axcount 70 mg	70 mg	Tablet	Oral Use
DE - Germany	Basics GmbH Hemmelrather Weg 201 D-51377 Leverkusen	ALENDRONSÄURE BASICS einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg	Alendron beta einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg	Alendron 10 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	biomo pharma GmbH Josef-Diezgen-Str 3 D-53773 Hennef	Alendronsäure-biomo 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Bluefish Pharmaceuticals AB Torsgatan 11 S-111 23 Stockholm	Alendronsäure Bluefish 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	CT Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin	Alendronsäure-CT 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	esparma GmbH Seepark 7 D-39116 Magdeburg	Alendron esparma 70 mg einmal wöchentlich Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Gedeon Richter Plc. Gyömrői út 19 - 21 H-1103 Budapest	Alendronate Richter 70 mg Filmtabletten	70 mg	Film-coated tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg	Alendronsäure Heumann 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg	Alendronsäure Heumann 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Alendron-Hexal 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Alendron-Hexal 10 einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Juta Pharma GmbH Gutenbergstr. 13 D-24941 Flensburg	Alendro-Q 70 mg Tablette	70 mg	Tablet	Oral Use
DE - Germany	Juta Pharma GmbH Gutenbergstr. 13 D-24941 Flensburg	Alendro-Q 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	KSK-Pharma Vertriebs AG Finkenstr. 1 D-76327 Pfinztal- Berghausen	Alendro-KSK 70 mg	70 mg	Tablet	Oral Use
DE - Germany	mibe GmbH Arzneimittel Münchener Str. 15 D-06796 Brehna	Alendromed 70 mg	70 mg	Tablet	Oral Use
DE - Germany	MSD Sharp & Dohme GmbH Lindenplatz 1 D-85540 Haar	FOSAMAX 10mg Tabletten	10 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	MSD Sharp & Dohme GmbH Lindenplatz 1 D-85540 Haar	FOSAMAX einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt	Alendronsäure Mylan 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt	Alendrosäure dura 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt	Alendrossa 10 mg	10 mg	Tablet	Oral Use
DE - Germany	Orion Corporation Orionintie 1 FIN-2200 ESPOO	Alendronsäure Orion 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Ovamex Limited 118 larch crescent GB-UB4 9EB HAYES, MIDDLESEX	Alendronsäure Ovamex 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Ovamex Limited 118 larch crescent GB-UB4 9EB HAYES, MIDDLESEX	Alendronsäure Ovamex 10 mg Tabletten	10 mg	Tablet	Oral Use
DE - Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm	Alendronsäure- ratiopharm 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen	Alendron-Sandoz einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel	Alendronsäure STADA 10 mg Tabletten	10 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel	Alendronsäure STADA 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Winthrop Arzneimittel GmbH Urmitzer Str. 5 D-56218 Mülheim-Kärlich	Alendron Winthrop einmal wöchentlich 70 mg Tabletten	70 mg	Tablet	Oral Use
DE - Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt	Alendrokit dura	91,36 mg 1495,5 mg 4 mg	Tablet and film-coated tablet	Oral Use
DE - Germany	TECNIMEDE - Sociedade Técnico-Medicinal, S.A. (BS 2) Rua da Tapada Grande, n2 P-2710-089 ABRUNHEIRA, SINTRA	Alendronsäure Tecnimede 70 mg Filmtabletten	70 mg	Film-coated tablet	Oral Use
DE - Germany	Volkspharma GmbH August-Wessels-Str. 5 D-86154 Augsburg	Alendronsäure 70 mg Volkspharma Tabletten	70 mg	Tablet	Oral Use
DK - Denmark	1A Farma, Herstedøstervej 27-29, DK-2620 Albertslund, Denmark	Alendronat "1A Farma"	70 mg	Film-coated tablets	Oral Use
DK - Denmark	Actavis Group PTC ehf., Reykjavíkurvegi 76-78, P.O. 425, IS-220 Hafnarfjörður, Iceland	Alendronat "Actavis"	70 mg	Tablets	Oral Use
DK - Denmark	Arrow Generics Limited, Unit 2, Eastman Way Stevenage, SG1 4SZ Hertfordshire, England	Alendronat "Arrow"	10 mg	Tablets	Oral Use
DK - Denmark	Arrow Generics Limited, Unit 2, Eastman Way Stevenage, SG1 4SZ Hertfordshire, England	Alendronat "Arrow"	70 mg	Tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	BLUEFISH PHARMACEUTICALS AB, Torsgatan 11, 111 23 Stockholm, Sweden	Alendronat "Bluefish"	70 mg	Tablets	Oral Use
DK - Denmark	Mylan AB, P.O.box 23033, Ynglingagatan 14, SE-104 35 Stockholm; Sweden	Alendronat "Mylan"	10 mg	Tablets	Oral Use
DK - Denmark	Mylan AB, P.O.box 23033, Ynglingagatan 14, SE-104 35 Stockholm; Sweden	Alendronat "Mylan"	70 mg	Tablets	Oral Use
DK - Denmark	Orifarm Generics A/S, Energivej 15, DK-5260 Odense S., Denmark	Alendronat "Orifarm"	70 mg	Tablets	Oral Use
DK - Denmark	Orion Corporation Orion Pharma, Orionintie 1, FI- 02200 Espoo, Finland	Alendronat "Orion"	70 mg	Tablets	Oral Use
DK - Denmark	Pharmachemie B.V., PO Box 552, Swensweg 5, NL-2031 GA Haarlem, Netherlands	Alendronat "PCH"	10 mg	Tablets	Oral Use
DK - Denmark	Ranbaxy (UK) Ltd., 20 Balderton Street, W1K 6TL London, UK	Alendronat "Ranbaxy"	70 mg	Tablets	Oral Use
DK - Denmark	Sandoz A/S, C.F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark	Alendronat "Sandoz"	70 mg	Film-coated tablets	Oral Use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Alendronat "Stada"	70 mg	Tablets	Oral Use
DK - Denmark	Teva Denmark A/S, Parallelvej 10-12, DK-2800 Kongens Lyngby, Denmark	Alendronat "Teva"	70 mg	Tablets	Oral Use
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Alendronat "ratiopharm"	70 mg	Tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Merck Sharp & Dohme B.V., PO Box 581, Waarderweg 39, NL-2031 BN Haarlem, Nederlands	Fasamax Ugetablet	70 mg	Tablets	Oral Use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Alendronat "Stada"	10 mg	Tablets	Oral Use
DK - Denmark	Teva Denmark A/S, Parallelsvej 10-12, DK-2800 Kongens Lyngby, Denmark	Alendronat "Teva"	10 mg	Tablets	Oral Use
EL - Greece	VIANEX S.A. TATIOIOU STREET Nea Erythrea 14671	FOSAMAX	10 MG/TAB	TABLET	Oral Use
EL - Greece	VIANEX S.A. TATIOIOU STREET Nea Erythrea 14671	FOSAMAX	5 MG/TAB	TABLET	Oral Use
EL - Greece	VIANEX S.A. TATIOIOU STREET Nea Erythrea 14671	FOSAMAX ONCE WEEKLY	70 MG/TAB	TABLET	Oral Use
EL - Greece	FARAN ABEE PRODUCTION AND COMMERCE OF MEDICINAL PRODUCTS ACHAIAS AND TROIZINIAS, KIFISSIA 14564	OSASTON	70 MG/TAB	TABLET	Oral Use
EL - Greece	BIOMEDICA-CHEMICA S.A. G. LYRA 25 KATW KIFISSIA	AMPINE	70 MG/TAB	TABLET	Oral Use
EL - Greece	KLEVA AFBEE PARNITHOS AVENUE 189 ACHARNES ATTIKIS 13675	DARGOL	70 MG/TAB	TABLET	Oral Use
EL - Greece	MED-ONE AFBEE AGIOU PETROU 30 & EPAMEINONDA ACHARNES 13675	DEBENAL	70 MG/TAB	TABLET	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	GENERICS PHARMA HELLAS ΕΠΕ VOULIAGMENIS AVENUE 577A 16451 ARGYROUPOLI P.O. BOX 72571	ALENDRONATE / GENERICS	70 MG/TAB	TABLET	Oral Use
EL - Greece	GENERICS PHARMA HELLAS ΕΠΕ VOULIAGMENIS AVENUE 577A 16451 ARGYROUPOLI P.O. BOX 72572	ALENDRONATE / GENERICS	10 MG/TAB	TABLET	Oral Use
EL - Greece	ALAPIS ABEE AUTOKRATOROS NIKOLAOU 2 ATHENS 17671	MELDOZ	70 MG/TAB	TABLET	Oral Use
EL - Greece	VELKA HELLAS AEBE KAPODISTRIOU AND KORINTHOU 12 NEO PSYCHIKO 15451	OSTAVEN	70 MG/TAB	TABLET	Oral Use
EL - Greece	ARROW GENERICS LIMITED, HERTS, UNITED KINGDOM Unit 2, Eastman Way, Stevenage, Herts United Kingdom	ALENDRONIC ACID/ARROW	10 MG/TAB	TABLET	Oral Use
EL - Greece	ARROW GENERICS LIMITED, HERTS, UNITED KINGDOM Unit 2, Eastman Way, Stevenage, Herts United Kingdom	ALENDRONIC ACID/ARROW	70 MG/TAB	TABLET	Oral Use
EL - Greece	PHARMANEL PHARMACEUTICALS S.A. MARATHONOS 106, GERAKAS 15344	OSTEONAT	70 MG/TAB	TABLET	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	MEDARTE PHARMACEUTICALS ABEE SPYROU VRETTOU 10 METAMORFOSI 14452	OSTALERT	70 MG/TAB	TABLET	Oral Use
EL - Greece	VOCATE PHARMACEUTICALS S.A. GOUNARI 150, GLYFADA 16674	FOSAZOM	70 MG/TAB	TABLET	Oral Use
EL - Greece	GENEPHARM S.A. 18km MARATHONOS AVENUE PALLINI ATTIKIS 15351	FOSALEN	70 MG/TAB	TABLET	Oral Use
EL - Greece	SANTA PHARMA S.A. ASKLIPIOU 4 KRYONERI ATTIKIS 14568	ALEFOS	70 MG/TAB	TABLET	Oral Use
EL - Greece	IASIS PHARMAC.HELLAS 137 FYLIS AVENUE KAMATERO 13451	LEDRONIN	70 MG/TAB	TABLET	Oral Use
EL - Greece	PHARMANEL PHARMACEUTICALS S.A. MARATHONOS 106, GERAKAS 15344	DIFONATE	70 MG/TAB	TABLET	Oral Use
EL - Greece	ANFARM HELLAS S.A. PERIKLEOUS 53-57 GERAKAS ATTIKIS 15344	RIDON	70 MG/TAB	TABLET	Oral Use
EL - Greece	AURORA PHARMACEUTICALS S.A. EVROU 4 & MESSINIAS 2 GERAKAS 15344	AURODREN	70 MG/TAB	TABLET	Oral Use
EL - Greece	VIOFAR LTD ETHNIKIS ANTISTASEWS & TRIZINIAS ACHARNES 13671	DEPAREX	70 MG/TAB	TABLET	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	BIOSPRAY ABEE 18KM MARATHONOS AVENUE PALLINI 15344	ALENDRAL	70 MG/TAB	TABLET	Oral Use
EL - Greece	FARMATHEN HELLAS ABEE MARATHONOS AVENUE 144 PALLINI 15351	POROCALM	70 MG/TAB	TABLET	Oral Use
EL - Greece	SANDOZ GMBH, KUNDL, AUSTRIA Biochemiestrasse 10, A-6250, Kundl Tirol, Austria	FOROSA	70 MG/TAB	TABLET	Oral Use
EL - Greece	RAFARM AEBE KORINTHOU 12 NEO PSYCHIKO 15451	MOSMASS	70 MG/TAB	TABLET	Oral Use
EL - Greece	ROTTAPHARM HELLAS S.A. PRDUCTION AND COMMERCE OF PHARMACEUTICALS ACHAIAS AND TRIZINIAS NEA KIFISSIA 14564	LOZOSTUN	70 MG/TAB	TABLET	Oral Use
EL - Greece	DELEGANT HOLDINGS LTD, CYPRUS AGIAS ELENIS 36 COMMERCIAL CENTRE GALAXY 401 NICOSIA 1061 CYPRUS	DELFOZA	70 MG/TAB	TABLET	Oral Use
EL - Greece	SPECIFAR ABEE 28TH OCTOBER 1 AGIA VARVARA 123 51	DROFAZ	70 MG/TAB	TABLET	Oral Use
EL - Greece	EVANGELOS KALOFOLIAS & CO IAPHARM MENANDROU 54 ATHENS 10431	FOSANDRON	70 MG/TAB	TABLET	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	TARGET PHARMA LTD MENANDROU 54 ATHENS 10431	ARTHROPLUS	70 MG/TAB	TABLET	Oral Use
EL - Greece	VIVAX PHARMACEUTICALS LTD, DERVENAKION 38 GERAKAS ATTIKIS 15344	EN-POR	70 MG/TAB	TABLET	Oral Use
EL - Greece	PHARMANEL PHARMACEUTICALS S.A. MARATHONOS 106, GERAKAS 15344	MORALEN	70 MG/TAB	TABLET	Oral Use
EL - Greece	FARMEX S.A. KIFISSOU AVENUE 132 ATHENS 12131	ENIMON	70 MG/TAB	TABLET	Oral Use
EL - Greece	ALET PHARMACEUTICALS ABEE AIDINIOU 26, CHALANDRI 12461	ALEDROLET	70 MG/TAB	TABLET	Oral Use
EL - Greece	PHARMA LINE S.A. TH. PETALA 41 NEA CHALKIDONA 14343	ZULGAR	70 MG/TAB	TABLET	Oral Use
EL - Greece	VERISFIELD (UK) LTD, U.K. 41 Chalton street, London, NW1 1JD, United Kingdom	ZEMAROS	70 MG/TAB	TABLET	Oral Use
EL - Greece	HELP ABEE VALAORITOU 10 METAMORFOSI ATTIKIS 14452	OSTEOS	70 MG/TAB	TABLET	Oral Use
EL - Greece	FARMEDIA AE ATHINAS 22 & APOLLONOS GERAKAS ATTIKIS 15344	FARMEMAX	70 MG/TAB	TABLET	Oral Use
EL - Greece	FARMAZAK S.A. NAOISSIS 31 VOTANIKOS 10447	ZAKODRONATE	70 MG/TAB	TABLET	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	TEVA PHARMA B.V., UTRECHT, THE NETHERLANDS Computerweg 10, 3542 DR, Utrecht, The Netherlands	TEVANATE	70 MG/TAB	TABLET	Oral Use
ES - Spain	MERCK SHARP AND DOHME DE ESPAÑA, S.A. Josefa Valcarcel, 38 28027 MADRID	FOSAMAX Semanal 70 mg comprimidos	70 mg	Film coated tablet	Oral Use
ES - Spain	MERCK SHARP AND DOHME DE ESPAÑA, S.A. Josefa Valcarcel, 38 28027 MADRID	FOSAMAX 10 mg Comprimidos	10 mg	tablets	Oral Use
ES - Spain	MYLAN PHARMACEUTICALS, S.L. Plom 2-4, 5º Planta 08038 Barcelona	ÁCIDO ALENDRÓNICO SEMANAL MYLAN 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS ALTER, S.A. Mateo Inurria, 30 28036 Madrid	ÁCIDO ALENDRÓNICO SEMANAL ALTER 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	MERCK S.L. María de Molina, 40 28006 Madrid	CALBION SEMANAL 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS ALTER, S.A. Mateo Inurria, 30 28036 Madrid	BIFOAL SEMANAL 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIO STADA, S.L. Frederic Mompou, 5 08960 Sant Just Desvern Barcelona	ÁCIDO ALENDRÓNICO SEMANAL STADA 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	RATIOPHARM ESPAÑA, S.A. Avda. de Burgos, 16 D - 5ª Planta 28036 Madrid	ACIDO ALENDRONICO SEMANAL RATIOPHARM 70 mg comprimidos	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	LABORATORIOS EDIGEN, S.A Chile 8, 2º Oficina 203.Edificio Euromadrid 28290 Las Matas Madrid	ÁCIDO ALENDRÓNICO EDIGEN 10 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS EDIGEN, S.A Chile 8, 2º Oficina 203.Edificio Euromadrid 28290 Las Matas Madrid	ÁCIDO ALENDRÓNICO EDIGEN 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	TEVA GENERICOS ESPAÑOLA, S.L.Guzmán el Bueno 133, Edificio Britania 4ºIzq.28003 Madrid	ACIDO ALENDRONICO TEVA 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	MABO FARMA, S.ACarretera M-300 Km 30,500. 28802 Alcalá de Henares	ÁCIDO ALENDRÓNICO SEMANTAL MABO 70 mg COMPRIMIDOS	70 mg	tablets	Oral Use
ES - Spain	CANTABRIA PHARMA, S.L.c/ Ribera del Loira, 46 edificio 2 28042 Madrid Spain	ALENDROCARE SEMANTAL 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	SANDOZ FARMACEUTICA, S.A.Avda. Osa Mayor, 4Aravaca 28023 (Madrid)	ÁCIDO ALENDRÓNICO SEMANTAL SANDOZ 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS NORMON, S.A.Ronda de Valdecarrizo, 6 28760 Tres Cantos	ACIDO ALENDRONICO SEMANTAL NORMON 70 mg Comprimidos	70 mg	tablets	Oral Use
ES - Spain	TECNIMEDE ESPAÑA, INDUSTRIA FARMACEUTICA, S.A. Avda. Pío XII, 92, Edificio Ural A, Planta 16-4 28036 Madrid	ACIDO ALENDRONICO SEMANTAL TECNIGEN 70 mg comprimidos	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	PHARMAGENUS, S.A. Avda. Camí Real, 51-57 08184 Palau-solita i Plegamans Barcelona	ACIDO ALENDRONICO SEMANAL PHARMAGENUS 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS RANBAXY, S.L.Passeig de Gracia, 9 08007 Barcelona	ÁCIDO ALENDRÓNICO SEMANAL RANBAXY 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	TEVA PHARMA S.L.U. C/ Anabel Segura, 11, Edificio Albatros B, 1ª planta 28108 Alcobendas	SEMANDROL SEMANAL 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	QUALIGEN, S.L.Avda. Barcelona, 69 08970 Sant Joan Despi	ACIDO ALENDRÓNICO SEMANAL QUALIGEN 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS DAVUR, S.L.Teide, 4-planta baja. Poligono Empresarial La Marina 28703 San Sebastian de los Reyes	ÁCIDO ALENDRÓNICO SEMANAL DAVUR 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	RIMAFAR, S.L.Pol. Ind. Malpica Calle C, Nº 4 50016 Zaragoza	ÁCIDO ALENDRÓNICO SEMANAL RIMAFAR 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	KERN PHARMA, S.L.Venus, 72. Poligono Industrial Colon II.08228 Tarrasa	ÁCIDO ALENDRÓNICO SEMANAL KERN PHARMA 70 mg Comprimidos	70 mg	tablets	Oral Use
ES - Spain	KORHISPANA S.L.Carretera de Castellvell, 24 43206 Reus	ACIDO ALENDRONICO SEMANAL KORHISPANA 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	GERVASI FARMACIA, S.L.Juan XXIII, 15-19 08950 Esplugues de Llobregat	LEFOSAN SEMANAL 70 mg comprimidos	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	LABORATORIOS ALACAN INDUSTRIAS QUIMICO FARMACEUTICAS, S.A.Sagitario, 14 03006 Alicante	ADELAN SEMANAL 70 mg Comprimidos	70 mg	tablets	Oral Use
ES - Spain	FARMALIDER, S.A.Aragoneses, 15 28108 Alcobendas	ACIDO ALENDRONICO SEMANAL FARMALIDER 70 mg comprimidos recubiertos con película	70 mg	Film coated tablets	Oral Use
ES - Spain	SINTEXLINE S.A.Polígono Industrial La Red, Calle 11 nº 2 41500 Alcalá de Guadaira	ALENDROGYN 70 mg comprimidos recubiertos con película	70 mg	Film coated tablets	Oral Use
ES - Spain	FARMALIDER, S.A.Aragoneses, 15 28108 Alcobendas	ALENDROFARM 70 mg comprimidos recubiertos con película	70 mg	Film coated tablets	Oral Use
ES - Spain	LABORATORIOS COMBIX, S.L.San Rafael, 3. Pol. Industrial Alcobendas 28108 Alcobendas	ACIDO ALENDRONICO SEMANAL COMBIX 70 mg comprimidos recubiertos con película	70 mg	Film coated tablets	Oral Use
ES - Spain	ALMUS FARMACEUTICA, S.A.Avda. Verge de Montserrat, 6 08820 El Prat de Llobregat	ACIDO ALENDRONICO SEMANAL ALMUS 70 mg comprimidos recubiertos con película	70 mg	Film coated tablets	Oral Use
ES - Spain	PENSA PHARMA, S.A.U Jorge Comín (médico pediatra), 3 - bajos 46015 Valencia	ACIDO ALENDRONICO SEMANAL PENSA 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS RANBAXY, S.L.Passeig de Gracia, 9 08007 Barcelona	ACIDO ALENDRONICO SEMANAL RANBAXYGEN 70 mg Comprimidos	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	LABORATORIOS RANBAXY, S.L.Passeig de Gracia, 9 08007 Barcelona	ÁCIDO ALENDRÓNICO SEMANTAL CINFA 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LAREQ PHARMA S.L Laguna, 66-68-70. Poligono Industrial Urtinsa II 28923 Alcorcón	ACIDO ALENDRONICO SEMANTAL LAREQ 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	LABORATORIOS PEREZ GIMENEZ, S.A.Pol. Ind. Los Mochos. Polígono 8 - Parcela 20. Crta. A-431, Km 19 14720 Almodovar del Río	ÁCIDO ALENDRÓNICO SEMANTAL CUVE 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	INDUSTRIA QUIMICA Y FARMACEUTICA VIR, S.A.Laguna, 66-68-70. Poligono Industrial Urtinsa II 28923 Alcorcón	ACIDO ALENDRONICO SEMANTAL VIR 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	BEXAL FARMACEUTICA, S.A Centro Empresarial Osa Mayor. Avda. Osa Mayor, 4 - Area B Aravaca (Madrid)	ACIDO ALENDRONICO SEMANTAL BEXAL 70 mg comprimidos recubiertos con película	70 mg	tablets	Oral Use
ES - Spain	ACOST COMERCIAL GENERIC-PHARMA, S.L.Centro Empresarial Osa Mayor. Osa Mayor, 4 Area B Aravaca (Madrid)	ACIDO ALENDRONICO SEMANTAL ACOST 70 mg comprimidos recubiertos con película	70 mg	tablets	Oral Use
ES - Spain	INDUSTRIA QUIMICA Y FARMACEUTICA VIR, S.A.Laguna, 66-68-70. Poligono Industrial Urtinsa II 28923 Alcorcón	ALENVIR SEMANTAL 70 mg comprimidos	70 mg	tablets	Oral Use
ES - Spain	Apotex Europe BV Darwinweg 20 2333 CR Leiden Netherlands	ÁCIDO ALENDRÓNICO APOTEX 70 mg comprimidos	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ET - Estonia	Merck Sharp & Dohme OÜ Peterburi tee 46 11415 Tallinn ESTONIA	FOSAMAX 70 MG	70 mg	Tablet	Oral Use
ET - Estonia	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow HA1 4HF, Middlesex UNITED KINGDOM	ALENDRONIC ACID ACCORD 70MG	70 mg	Tablet	Oral Use
ET - Estonia	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow HA1 4HF, Middlesex UNITED KINGDOM	ALENDRONIC ACID ACCORD 10MG	10mg	Tablet	Oral Use
ET - Estonia	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður ICELAND	LENDRATE	70 mg	Tablet	Oral Use
ET - Estonia	Gedeon Richter Plc. Gyömrői út 19-21 1103 Budapest HUNGARY	SEDRON	70 mg	Film-coated tablet	Oral Use
ET - Estonia	KRKA d.d., Novo Mesto Šmarjenska cesta 6, 8501 Novo Mesto SLOVENIA	LINDRON	10mg	Tablet	Oral Use
ET - Estonia	MEPHA Lda. Lagoas Park Edifício 5-A, Piso 2, 2740-298 Porto Salvo PORTUGAL	DENSIDRON	70 mg	Film-coated tablet	Oral Use
ET - Estonia	Orion Corporation Orionintie 1 FIN-02200 Espoo FINLAND	ALENDROONHAPE ORION	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ET - Estonia	Ranbaxy (UK) Limited 20 Balderton Street, London W1K 6TL UNITED KINGDOM	RALENOST 70MG	70 mg	Tablet	Oral Use
ET - Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht THE NETHERLANDS	ALENOTOP	70 mg	Tablet	Oral Use
ET - Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht THE NETHERLANDS	TEVANATE 70 MG	70 mg	Tablet	Oral Use
FI - Finland	Ranbaxy UK Ltd, 20 Balderton Street, LONDON W1K 6TL, United Kingdom	Alendronat Ranbaxy	70 mg	tablet	Oral Use
FI - Finland	Actavis Group PTC ehf, Reykjavikurvegi 76-78, 220 HAFNARFJORDUR, Iceland	Alendronat Actavis	70 mg	tablet	Oral Use
FI - Finland	Arrow Generics Limited, Unit 2, Eastman Way Stevenage, HERTS SG14SZ, United Kingdom	Alendronat Arrow	10 mg	tablet	Oral Use
FI - Finland	Arrow Generics Limited, Unit 2, Eastman Way Stevenage, HERTS SG14SZ, United Kingdom	Alendronat Arrow	70 mg	tablet	Oral Use
FI - Finland	Bluefish Pharmaceuticals AB, Torsgatan 11, 11123 STOCKHOLM, Sweden	Alendronat Bluefish	70 mg	tablet	Oral Use
FI - Finland	Hexal A/S, Kanalholmen 8- 12, 2650 HVIDOVRE, Denmark	Alendronat Hexal	70 mg	film-coated tablet	Oral Use
FI - Finland	Mylan AB, BOX 23033, 10435 STOCKHOLM, Sweden	Alendronat Mylan	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FI - Finland	Orifarm Generics A/S, Energivej 15, 5260 ODENSE S, Denmark	Alendronat Orifarm	70 mg	tablet	Oral Use
FI - Finland	Orion Corporation, Orion Pharma, Orionintie 1, 02200 Espoo, Finland	Alendronat Orion	70 mg	tablet	Oral Use
FI - Finland	ratiopharm GmbH, Graf- Arco-Strasse 3, 89079 Ulm, Germany	Alendronat ratiopharm	70 mg	film-coated tablet	Oral Use
FI - Finland	Sandoz A/S, C. F. Tietgens Boulevard 40, 5220 ODENSE SØ, Denmark	Alendronat Sandoz	70 mg	film-coated tablet	Oral Use
FI - Finland	Merck Sharp & Dohme B.V., Waarderweg 39, P.O.BOX 581, 2031 BN HAARLEM, Netherlands	Fosamax	10 mg	tablet	Oral Use
FI - Finland	Merck Sharp & Dohme B.V., Waarderweg 39, P.O.BOX 581, 2031 BN HAARLEM, Netherlands	Fosamax	70 mg	tablet	Oral Use
FR - France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	ACIDE ALENDRONIQUE ALMUS 10 mg, comprimé	10 mg	tablet	Oral Use
FR - France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	ACIDE ALENDRONIQUE ALMUS 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	ALTER 3, avenue de la Baltique ZI de Courtaboeuf 91140 Villebon Sur Yvette FRANCE	ACIDE ALENDRONIQUE ALTER 70 mg, comprimé pelliculé	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	ACIDE ALENDRONIQUE ARROW 10 mg, comprimé	10 mg	tablet	Oral Use
FR - France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	ACIDE ALENDRONIQUE ARROW 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	ACIDE ALENDRONIQUE BIOGARAN 10 mg, comprimé	10 mg	tablet	Oral Use
FR - France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	ACIDE ALENDRONIQUE BIOGARAN 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	EG LABO - LABORATOIRES EUROGENERICS "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex FRANCE	ACIDE ALENDRONIQUE EG 10 mg, comprimé	10 mg	tablet	Oral Use
FR - France	EG LABO - LABORATOIRES EUROGENERICS "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex FRANCE	ACIDE ALENDRONIQUE EG 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	ACIDE ALENDRONIQUE MYLAN, 70 mg, comprimé	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex FRANCE	ACIDE ALENDRONIQUE PHR LAB 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	KROMME RIJN APOTHEEK Langstraat 4C 3981 EV BUNNIK PAYS-BAS	ACIDE ALENDRONIQUE QUALIHEALTH 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	QUALIMED (LYON) 117, allée des Parcs 69800 Saint-Priest FRANCE	ACIDE ALENDRONIQUE QUALIMED 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	RATIOPHARM (ALLEMAGNE) Graf Arco Strasse 3 89079 Ulm ALLEMAGNE	ACIDE ALENDRONIQUE RATIOPHARM 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	ACIDE ALENDRONIQUE SANDOZ 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	ACIDE ALENDRONIQUE WINTHROP 10 mg, comprimé	10 mg	tablet	Oral Use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	ACIDE ALENDRONIQUE WINTHROP 70 mg, comprimé	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	ZYDUS FRANCE 25, rue des Peupliers ZAC Les Hautes Pâtures - Parc d'Activités des Peupliers 92000 Nanterre FRANCE	ACIDE ALENDRONIQUE ZYDUS 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	PHARMEMMA Unit 2, Ashbourne Manufacturing Park Ashbourne County Meath IRLANDE	ARONADE 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	THERAMEX 6, avenue Albert II Zone F - Bloc B 98000 Monaco MONACO	AURENA 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	PHARMEMMA Unit 2, Ashbourne Manufacturing Park Ashbourne County Meath IRLANDE	DRONACID 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	MERCK SHARP & DOHME CHIBRET 3, avenue Hoche 75114 Paris Cedex 08 FRANCE	FOSAMAX 10 mg, comprimé	70 mg	tablet	Oral Use
FR - France	MERCK SHARP & DOHME CHIBRET 3, avenue Hoche 75114 Paris Cedex 08 FRANCE	FOSAMAX 70 mg, comprimé	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	MERCK SHARP & DOHME CHIBRET 3, avenue Hoche 75114 Paris Cedex 08 FRANCE	FOSATROL 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 Puteaux FRANCE	ACIDE ALENDRONIQUE BIOGALENIQUE 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	LABORATOIRE RPG - RANBAXY PHARMACIE GENERIQUES 4, place Louis Armand 75012 Paris FRANCE	ACIDE ALENDRONIQUE RANBAXY 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 Puteaux FRANCE	ACIDE ALENDRONIQUE RPG 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex FRANCE	ACIDE ALENDRONIQUE TEVA 70 mg, comprimé	70 mg	tablet	Oral Use
FR - France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex FRANCE	ALENDRONATE TEVA 10 mg, comprimé	10 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Generics (UK) Ltd. Albany Gate, Darkes Lane, Potters bar EN61AG Hertfordshire UK	ALENDIS 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate]	tablet	Oral Use
HU - Hungary	Arrow Generics Ltd. Stevenage SG14SZ Hertfordshire UK	ALENDROMAX 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.36 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Sandoz Hungária Kft., 1114 Budapest, Bartók Béla út 43-47. Hungary	ALENDRON HEXAL 70 mg tablettá	70.0 mg Alendronic acid [in the form of 91.36 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Bluefish Pharmaceuticals ABTorsgatan 11 111 23 Stockholm Sweden	ALENDRONAT BLUEFISH 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate trihydrate]	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Orion Corporation Orionintie 1. 2200 Espoo Finland	ALENDRONAT ORION 70 mg tableta	70.0 mg Alendronic acid [in the form of 91.36 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Pliva Hungária Kft. Galagonya u. 5. 1036 Budapest Hungary (The company is the member of TEVA Group Teva Magyarország zRt,1134budapest, Róbert Károly krt.59))	ALENDRONAT PLIVA 70 mg tableta	70.0 mg Alendronic acid [in the form of 91.36 mg alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Ratiopharm Hungária Kft. Uzsoki u. 36/A 1145 Budapest Hungary	ALENDRONAT- RATIOPHARM 70 mg tableta	70.0 mg Alendronic acid [in the form of 91.36 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	ALENDRONAT- RICHTER 70 mg filmtableta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film coated tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Sandoz Hungária Kft., 1114 Budapest, Bartók Béla út 43-47. Hungary	ALENDRONAT- SANDOZ 70 mg filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate]	film coated tablet	Oral Use
HU - Hungary	Apotex Europe B.V. Darwinweg 20. 2333 CR Leiden Holland	ALENDRONSAV APOTEX 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	Calcisedron-D filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film-coated tablet	Oral Use
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	Calcisedron-D Trio filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film-coated tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Aramis Pharma Kft. Mester u. 28. III/5. 1095 Budapest Hungary	DRONAVIC 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Apotex Europe B.V. Darwinweg 20. 2333 CR Leiden Holland	EPOLAR 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate]	tablet	Oral Use
HU - Hungary	Apotex Europe B.V. Darwinweg 20. 2333 CR Leiden Holland	EPOLAR Trio 70 mg tabletta és rágótabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate]	tablet and chewing tablet	Oral Use
HU - Hungary	Actavis Group PTC ehf. Reykjavíkurvegur 76-78. 220 Hafnarfjörður Iceland	FLADOR 70 mg tabletta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate trihydrate]	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Medico Uno Pharma Kft. Viadukt u. 12. 2051 Biatorbágy Hungary	FORTIMAX tableta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate trihydrate]	tablet	Oral Use
HU - Hungary	Merck Sharp & Dohme Magyarország Kft. Alkotás u. 48-50. 1123 Budapest Hungary	FOSAMAX 70 mg tableta	70.0 mg Alendronic acid [in the form of 91.37 mg sodium alendronate]	tablet	Oral Use
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	HANTRUX 70 mg filmtableta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film coated tablet	Oral Use
HU - Hungary	Vera Pharma Kft. Rákos köz 22. 1028 Budapest Hungary	MASSIDRON 70 mg tableta	70.0 mg Alendronic acid [in the form of 81.2 mg mg sodium alendronate monohydrate]	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	MATEKIT 70 mg filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film coated tablet	Oral Use
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	SEDRON 70 mg filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film coated tablet	Oral Use
HU - Hungary	Teva Magyarország Zrt. 2100 Gödöllő, Repülőtéri út 5.	TRABECAN-TEVA 70 mg tablettá	70.0 mg Alendronic acid [in the form of 81.2 mg mg sodium alendronate monohydrate]	tablet	Oral Use
HU - Hungary	Teva Magyarország Zrt. 2100 Gödöllő, Repülőtéri út 5.	TRABECAN Duo TEVA tablettá és lágy kapszula	70.0 mg Alendronic acid [in the form of 81.2 mg mg sodium alendronate monohydrate]	tablet and soft capsules	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Richter Gedeon nyrt. Gyömrői út 19-21. 1103 Budapest Hungary	UTERITRIN 70 mg filmtabletta	70.0 mg Alendronic acid [in the form of 91.35 mg sodium alendronate trihydrate]	film coated tablet	Oral Use
IE - Ireland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Fosamax	10mg	Tablet	Oral Use
IE - Ireland	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	Fosamax	70 mg	Tablet	Oral Use
IE - Ireland	Clonmel Healthcare Limited Waterford Road Clonmel Co. Tipperary Ireland	Osteomel Once weekly	70 mg	Tablet	Oral Use
IE - Ireland	PLIVA Pharma Ltd. Vision House Bedford Road Petersfield Hants, GU32 3QB United Kingdom	Fosalen Once Weekly 70mg Tablets	70 mg	Tablet	Oral Use
IE - Ireland	Rowex Ltd Bantry Co. Cork	Romax Once Weekly 70 mg Tablets	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Laboratorios Davur S.L.U. C/Anabel Segura 11 Edificio Albatros B 1a planta Alcobendas 28108 Madrid Spain	Alendronic Acid Once Weekly 70mg Tablets	70 mg	Tablet	Oral Use
IE - Ireland	McDermott Laboratories Ltd. t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13	Fostepor 10mg Tablets	10mg	tablets	Oral Use
IE - Ireland	McDermott Laboratories Ltd. t/a Gerard Laboratories 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13	Fostepor Once Weekly 70mg Tablets	10mg	tablets	Oral Use
IE - Ireland	PLIVA Pharma Ltd. Vision House, Bedford Road, Petersfield, Hants, GU32 3QB, United Kingdom	Fosalen 10 mg Tablets	10mg	tablets	Oral Use
IE - Ireland	PLIVA Pharma Ltd. Vision House, Bedford Road, Petersfield, Hants, GU32 3QB, United Kingdom	Fosalen Once Weekly 70mg Tablets	70mg	tablets	Oral Use
IE - Ireland	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, The Netherlands	Tevanate Once Weekly 70mg Tablets	70mg	Tablets	Oral Use
IE - Ireland	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, The Netherlands	Fosalen Once Weekly 70mg Tablets	70mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Bluefish Pharmaceuticals AB, Torsgatan 11, 111 23 Stockholm, Sweden.	Alendronic Acid Bluefish Once weekly 70 mg Tablets	70mg	tablets	Oral Use
IE - Ireland	Actavis Group PTC ehf; Reykjavíkurveg 76-78, 220 Hafnarfjörður Iceland	Fostolin Once Weekly 70mg Tablets	70 mg	tablets	Oral Use
IS - Iceland	Arrow Generics Ltd., Unit 2 Eastman Way Stevenage, Hertz SG1 4SZ U.K	Alendroarrow	10 mg	Tablet	Oral Use
IS - Iceland	Arrow Generics Ltd., Unit 2 Eastman Way Stevenage, Hertz SG1 4SZ U.K	Alendroarrow week tablet	70 mg	Tablet	Oral Use
IS - Iceland	Actavis Group PTC ehf., Reykjavíkurveg 76-78, 220 Hafnarfjörður, Iceland	Alendronat Actavis	70 mg	Tablet	Oral Use
IS - Iceland	Ranbaxy (UK) Limited, C.P. House 97-107 Uxbridge Road, Ealing Londo W5 5TL U.K	Alendronat Ranbaxy	70 mg	Tablet	Oral Use
IS - Iceland	Merck Sharp & Dohme B.V., Waarderveg 39, PC Haarlem, The Netherlands	Fosamax week tablet	70 mg	Tablet	Oral Use
IS - Iceland	Williams & Halls ehf, Hverfisgata 105 101 Reykjavík, Iceland	Ostacid	70 mg	film-coated tablet	Oral Use
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	ALENDROS	10 mg	tablets	Oral Use
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	ALENDROS	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	ACCORD HEALTHCARE LIMITED Sage House,319 Pinner Road North Harrow Middlesex	ALENDRONATO AHCL	10 mg	tablets	Oral use
IT - Italy	ACTAVIS GROUP PTC EHF Reykjavikurvegi 76-78	ALENDRONATO ACTAVIS	70 mg	tablets	Oral use
IT - Italy	AGIPS FARMACEUTICI Srl Via Amendola 4 - 16035 Rapallo (GE)	GLAMOR	70 mg	film coated tablets	Oral use
IT - Italy	ALMUS Srl Via Cesarea, 11/10 - 16121 Genova	ALENDRONATO ALMUS	70 mg	film coated tablets	Oral use
IT - Italy	ARROW GENERICS LTD Unit 2, Eastman way Stevenage, Herts SG1 4SZ	ALENDRONATO ARROW	10 MG	tablets	Oral use
IT - Italy	ARROW GENERICS LTD Unit 2, Eastman way Stevenage, Herts SG1 4SZ	ALENDRONATO ARROW	70 mg	tablets	Oral use
IT - Italy	BENTLEY PHARMACEUTICALS IRELAND LTD 25-28 North Wall Uay Dublin 1 - Ireland	ALENDRONATO BENTLEY PHARMACEUTICALS IRELAND	70 mg	tablets	Oral use
IT - Italy	BIOHEALTH PHARMACEUTICALS Srl Via Bolognese, 250 Pistoia - Italy	ASTON	70 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	BIOMEDICA FOSCAMA INDUSTRIA CHIMICA FARMACEUTICA SpA Via Morolense, 87 - 03013 Ferentino (FR)	ALOST	70 mg	tablets	Oral use
IT - Italy	LABORATORIO PRODOTTI FARMACEUTICI BONISCONTRO & GAZZONE Srl Via Pavia, 6 - 20136 Milano - Italy	DORYX	70 mg	tablets	Oral use
IT - Italy	DOC GENERICI Srl Via Manuzio, 7 - 20124 Milano	ALENDRONATO DOC GENERICI	70 mg	tablets	Oral use
IT - Italy	DOC GENERICI Srl Via Manuzio, 7 - 20124 Milano	ALENDRONATO DOC	70 mg	tablets	Oral use
IT - Italy	DR REDDY'S Srl Via Fernanada Wittgens, 6 - 20123 Milano	ALENDRONATO DR REDDY'S	70 mg	tablets	Oral use
IT - Italy	EG SpA Via Pavia, 6 - 20136 Milano - Italy	ALENDRONATO EG	10 mg	tablets	Oral use
IT - Italy	EG SpA Via Pavia, 6 - 20136 Milano - Italy	ALENDRONATO EG	70 mg	tablets	Oral use
IT - Italy	EPIFARMA Srl Via San Rocco, 6 - 85033 Episcopia (PZ)	ALENIC	70 mg	tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	EPIFARMA Srl Via San Rocco, 6 - 85033 Episcopia (PZ)	ACIDO ALENDRONICO EPIFARMA	70 mg	tablets	Oral use
IT - Italy	FG Srl Via San Rocco, 6 - 85033 Episcopia (PZ)	ACIDO ALENDRONICO FG	70 mg	tablets	Oral use
IT - Italy	FIDIA FARMACEUTICI SpA Via Ponte D/Fabbrica, 3/A - 25031 Abano Terme (PD)	ACIDO ALENDRONICO FIDIA	70 mg	tablets	Oral use
IT - Italy	GERMED PHARMA SpA Via Cesare Cantù, 11 - 20092 Cinisello Balsamo (MI)	ALENDRONATO GERMED	10 mg	tablets	Oral use
IT - Italy	GERMED PHARMA SpA Via Cesare Cantù, 11 - 20092 Cinisello Balsamo (MI)	ALENDRONATO GERMED	70 mg	tablets	Oral use
IT - Italy	HEXAL SpA Via Paracelso, 16 - 20041 Agrate Brianza (MI)	ALENDRONATO HEXAL	70 mg	tablets	Oral use
IT - Italy	ISTITUTO CHIMICO INTERNAZIONALE DR. GIUSEPPE RENDE Srl Via Salaria, 1240 - 00138 Roma	REALEN	70 mg	tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	ISTITUTO GENTILI SpA Via San Giuseppe Cottolengo, 15 - 20143 Milano	GENALEN	10 mg	tablets	Oral use
IT - Italy	ISTITUTO GENTILI SpA Via San Giuseppe Cottolengo, 15 - 20143 Milano	GENALEN	70 mg	tablets	Oral use
IT - Italy	LABORATORI ALTER Srl Via Lomellina, 39 - 20124 Milano	ALENDRONATO ALTER	70 mg	tablets	Oral use
IT - Italy	MERCK SHARP & DOHME Ltd Hertford Road, Hoddesdon Hertfordshire EN119BU	FOSAMAX	10 mg	tablets	Oral use
IT - Italy	MERCK SHARP & DOHME Ltd Hertford Road, Hoddesdon Hertfordshire EN119BU	FOSAMAX	70 mg	tablets	Oral use
IT - Italy	MYLAN SpA Via Vittor Pisani, 20 - 20124 Milano	ALENDRONATO MYLAN GENERICS	70 mg	tablets	Oral use
IT - Italy	NEOPHARMED Srl Via San Giuseppe Cottolengo, 15 - 20143 Milano	ADRONAT	10 mg	tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	NEOPHARMED Srl Via San Giuseppe Cottolengo, 15 - 20143 Milano	ADRONAT	70 mg	tablets	Oral use
IT - Italy	PENSA PHARMA SpA Via Rossellini Ippolito, 12 20124 - Milano	ALENDRONATO PENSA	70 mg	tablets	Oral use
IT - Italy	PHARMEG Srl Via dei Giardini, 24 - 85033 Episcopia (PZ)	PORODRON	70 mg	tablets	Oral use
IT - Italy	RANBAXY ITALIA SpA p.zza Filippo Meda, 3 - 20121 Milano	ALENDRONATO RANBAXY ITALIA	70 mg	tablets	Oral use
IT - Italy	RATIOPHARM GMBH Graf Arco-strasse, 3 Ulm D-89070	ALENDRONATO RATIOPHARM	70 mg	tablets	Oral use
IT - Italy	S.F.GROUP Srl Via Beniamino Segre, 59 00134 Roma Italy	NOFRATTIL	70 mg	film coated tablets	Oral use
IT - Italy	SANDOZ SpA L.go U. Boccioni, 1 - 21040 Origgio (VA)	ALENDRONATO SANDOZ	70 mg	tablets	Oral use
IT - Italy	SEGIX ITALIA Srl Via Del Mare, 36 - 00040 Pomezia (RM)	DRALENOS	10 mg	tablets	Oral use
IT - Italy	SEGIX ITALIA Srl Via Del Mare, 36 - 00040 Pomezia (RM)	DRALENOS	70 mg	tablets	Oral use
IT - Italy	SIGMA TAU GENERICS SpA Via Pontina Km30, 400 00040 Pomezia (RM)	ACIDO ALENDRONICO SIGMA TAU GENERICS	70 mg	tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE SpA Viale Shakespeare, 47 00144 Roma	DRONAL	10 mg	tablets	Oral use
IT - Italy	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE SpA Viale Shakespeare, 47 00144 Roma	DRONAL	70 mg	tablets	Oral use
IT - Italy	SO.SE.PHARM Srl Via dei Castelli Romani, 22 00040 Pomezia (RM)	LOSS	70 mg	film coated tablets	Oral use
IT - Italy	TEVA ITALIA Srl Via Messina, 38 - 20154 Milano - Italy	ALENDRONATO TEVA	70 mg	tablets	Oral use
IT - Italy	ACCORD HEALTHCARE LIMITED Sage House,319 Pinner Road North Harrow Middlesex	ALENDRONATO AHCL	70 mg	tablets	Oral use
LT - Lithuania	KRKA d.d., Šmarješka Cesta 6 8501 Novo mesto, Slovenia	Lindron	10 mg	Tablet	Oral use
LT - Lithuania	Sandoz d.d., Verovškova 57 SI-1000 Ljubljana Slovenia	Alendon	70 mg	Tablet	Oral use
LT - Lithuania	Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland	Lendrate	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LT - Lithuania	Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	Alendronic acid Accord	70 mg	Tablet	Oral use
LT - Lithuania	Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	Alendronic acid Accord	10 mg	Tablet	Oral use
LT - Lithuania	Teva Pharma B.V., Computerweg 10 3542 DR Utrecht, The Netherlands	Alenotop	70 mg	Tablet	Oral use
LT - Lithuania	Teva Pharma B.V., Computerweg 10 3542 DR Utrecht, The Netherlands	Tevanate	70 mg	Tablet	Oral use
LT - Lithuania	Mepha Lda., Lagoas Park, Edificio 5-A, Piso 2, 2740- 298 Porto Salvo, Portugal	Densidron	70 mg	Tablet	Oral use
LT - Lithuania	Ranbaxy UK Ltd., 20 Balderton Street London W1K 6TL, United Kingdom	Ralenost	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LT - Lithuania	Gedeon Richter Plc., 1103 Budapest Gyömrői út 19-21, Hungary	Sedron	70 mg	Film-coated tablet	Oral use
LT - Lithuania	Pharmaceutical Works POLPHARMA SA, 19 Pelplińska Street 83-200 Starogard Gdański, Poland	Ostemax	70 mg	Tablet	Oral use
LT - Lithuania	UAB „Merck Sharp & Dohme“, Kęstučio 59/27, LT-08124 Vilnius, Lithuania	Fosamax	70 mg	Tablet	Oral use
LT - Lithuania	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Alendorion	70 mg	Tablet	Oral use
LU - Luxembourg	Merck Sharp & Dohme 5, Clos du Linx B-1200 Bruxelles	Fosamax-70 Hebdomadaire	70 mg	tablets	Oral Use
LV - Latvia	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, united Kingdom	Alendronate sodium Accord	10 mg	tablets	Oral use
LV - Latvia	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, united Kingdom	Alendronate sodium Accord	70 mg	tablets	Oral use
LV - Latvia	Orion Corporation, Orionintie 1, FI-02200	Alendorion	70 mg	tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	Espoo Finland				
LV - Latvia	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, Netherlands	Alenotop	70 mg	tablets	Oral Use
LV - Latvia	Mepha Lda., Lagoas Park, 2740-298 Porto Salvo, Portugal	Densidron	70 mg	film-coated tablets	Oral Use
LV - Latvia	Gedeon Richter Plc., 1103 Budapest, Gyomroi ut 19- 21, Hungary	Sedron	70 mg	film-coated tablets	Oral Use
LV - Latvia	Pharmaceutical Works Polpharma SA., 19 Pelplinska Str., 83-200 Starogard Gdanski, Poland	Ostemax	70 mg	tablets	Oral Use
LV - Latvia	Actavis Group PTC ehf., Reykjavikurvegi 76-78, 220 Hafnarfjordur, Iceland	Lendrate	70 mg	tablets	Oral Use
LV - Latvia	SIA"Merck Sharp & Dohme Latvija", Skanstes iela 13, Riga LV-1013, Latvia	Fosamax	70 mg	tablets	Oral Use
MT - Malta	Mepha - Investigaçãõ, Desenvolvimento e Fabricaçãõ Farmaceutica, Lda.	Densidron	70mg	film-coated tablets	Oral Use
MT - Malta	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK	Fosamax	70mg	tablets	Oral Use
MT - Malta	Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United kingdom.	Alendronic Acid 10mg tablets	10mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
MT - Malta	Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United kingdom.	Alendronic Acid 70mg tablets	70mg	Tablet	Oral Use
MT - Malta	Aurobindo Pharma (Malta) Ltd, 46/2 South Street, Valletta VLT11, Malta	Alendronic Acid 70mg tablet	70mg	Tablet	Oral Use
MT - Malta	Accord Healthcare Limited Sage House 319, Pinner Road North Harrow Middlesex HA1 4 HF United Kingdom	Alendronate Sodium Accord 10 mg Tablets	10mg	Tablets	Oral Use
MT - Malta	Accord Healthcare Limited Sage House 319, Pinner Road North Harrow Middlesex HA1 4 HF United Kingdom	Alendronate Sodium Accord 70 mg Tablets	70mg	Tablets	Oral Use
MT - Malta	Actavis Group PTC ehf; Reykjavikurvegi 76-78, 220 Hafnarfjordur Iceland	Lendrate	70 mg	tablets	Oral Use
NL - Netherlands	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald, Germany	Osteonorm 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	ratiopharm Nederland bv Florapark 4 2012 HK Haarlem Netherlands	Alendroninezuur ratiopharm 70 mg	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Sandoz B.V., Veluwezoom 22 1327 AH Almere Netherlands	Alendroninezuur Sandoz 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Iono Limited 65 Delamere Road, Hayes Middlesex UB4 ONN United Kingdom	Alendroninezuur Iono 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Iono Limited 65 Delamere Road, Hayes Middlesex UB4 ONN United Kingdom	Alendroninezuur Iono 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem Netherlands	Alendroninezuur 10 PCH	10 mg	Tablet	Oral Use
NL - Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem Netherlands	Alendroninezuur 70 PCH	70 mg	Tablet	Oral Use
NL - Netherlands	Centrafarm Services B.V. Nieuwe Donk 9 47879 AC Etten-Leur Netherlands	Alendroninezuur CF 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Genericon Pharma Gesellschaft m.b.H. Hafnerstraße 211 8054 Graz Austria	Alendronorm 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Bentley Pharmaceuticals Limited, 25/28 North Wall Quay Dublin 1 Ireland	Alendroninezuur Bentley 70 mg	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Biomedica Foscoma Industria Chimico- Farmaceutica S.p.A. Via Morolense, 87 - 03010 Ferentino	Dronatex 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Arrow Generics Limited Unit 2, Eastman Way, Stevenage, Hertfordshire, SG1 4SZ United Kingdom	Alendroninezuur Arrow 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Apotex Europe BV Darwinweg 20 2333 CR Leiden Netherlands	Alendroninezuur Apotex 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Ranbaxy Belgium NV Leuvensestraat 28b 1800 Vilvoorde Belgium	Alendratol 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Ranbaxy Belgium NV Leuvensestraat 28b 1800 Vilvoorde Belgium	Alendratol 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Ranbaxy Belgium NV Leuvensestraat 28b 1800 Vilvoorde Belgium	Randronate 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Sandoz B.V., Veluwezoom 22 1327 AH Almere Netherlands	Alendroninezuur Sandoz 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Sandoz B.V., Veluwezoom 22 1327 AH Almere Netherlands	Alendroninezuur Sandoz 70 mg	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Mylan BV Dieselweg 25 3752 LB Bunschoten Netherlands	Alendroninezuur Mylan 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Mylan BV Dieselweg 25 3752 LB Bunschoten Netherlands	Alendroninezuur Mylan 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Apothecon B.V. Nijverheidsweg 3, 3771 ME Barneveld Netherlands	Alendroninezuur 70A	70 mg	Tablet	Oral Use
NL - Netherlands	mibe GmbH Arzneimittel Münchener Str. 15 06796 Brehna Germany	Ostadil 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Actavis Group PTC ehf Reykjavíkurvegur 76-78,220 Hafnarfjörður	Alendroninezuur Actavis 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Centrafarm Services B.V. Nieuwe Donk 9 47879 AC Etten-Leur Netherlands	Alendroninezuur CF 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Bluefish Pharmaceuticals AB, Torsgatan 11 111 23 Stockholm Sweden	Akendroninezuur Bluefish 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	WILL-PHARMA Wilgenlaan 5 1161 JK Zwanenburg Netherlands	Bonendro	70 mg / 1000 mg / 880 IU	Tablet + granulate combination package	Oral Use
NL - Netherlands	Merck Sharp & Dohme BV Waarderweg 39 2031 BN Haarlem Netherlands	Fosamax 10 mg	10 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Merck Sharp & Dohme BV Waarderweg 39 2031 BN Haarlem Netherlands	Fosamax 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	WILL-PHARMA Wilgenlaan 5 1161 JK Zwanenburg Netherlands	Alendronax 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Accord Healthcare Limited, Sage House, 319, Pinner Road, North Harrow, Middlesex HA1 4HF United Kingdom	Alendroninezuur Accord 10 mg	10 mg	Tablet	Oral Use
NL - Netherlands	Accord Healthcare Limited, Sage House, 319, Pinner Road, North Harrow, Middlesex HA1 4HF United Kingdom	Alendroninezuur Accord 70 mg	70 mg	Tablet	Oral Use
NL - Netherlands	Ranbaxy Belgium NV Leuvensestraat 28b 1800 Vilvoorde Belgium	Alendroninezuur 70 Ranbaxy	70 mg	Tablet	Oral Use
NO - Norway	Arrow Generics Ltd, 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, united Kingdom	Alendronat Arrow	10 mg	Tablet	Oral Use
NO - Norway	Arrow Generics Ltd, 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, united Kingdom	Alendronat Arrow	70 mg	Tablet	Oral Use
NO - Norway	ratiopharm GmbH, Graf- Arco-Strasse 3, D-89070 Ulm Germany	Alendronate ratiopharm	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NO - Norway	Merck Sharp and Dohme B.V., Postbus 581, Waarderweg 39, Haarlem, NL-2003 PC, Netherlands	Fosamax	10 mg	Tablet	Oral Use
NO - Norway	Merck Sharp and Dohme B.V., Postbus 581, Waarderweg 39, Haarlem, NL-2003 PC, Netherlands	Fosamax	70 mg	Tablet	Oral Use
NO - Norway	Bluefish Pharmaceuticals AB Torsgatan 11, SE-11123 Stockholm, Sweden	Alendronat Bluefish	70 mg	tablet	Oral Use
NO - Norway	Mylan AB, Box 23033, 10435 Stockholm, Sweden	Alendronat Mylan	70 mg	Tablet	Oral Use
NO - Norway	Mylan AB, Box 23033, 10435 Stockholm, Sweden	Alendronat Mylan	70 mg	Tablet	Oral Use
NO - Norway	Sandoz A/S, Edvard Thomsens Vej 14, DK-2300 København S, Danmark	Alendronat Sandoz	70 mg	Tablet	Oral Use
NO - Norway	Teva Sweden AB, Box 1070, 25110 Helsingborg, Sweden	Alendronat Teva	10 mg	Tablet	Oral Use
NO - Norway	Teva Sweden AB, Box 1070, 25110 Helsingborg, Sweden	Alendronat Teva	70 mg	Tablet	Oral Use
PL - Poland	Polfarmex S.A. Józefów st. 9 99-300 Kutno, Poland	Akost	70 mg + 91,37 mg	tablets	Oral Use
PL - Poland	Sandoz GmbH Biochemiestrasse 10, A- 6250 Kundl, Austria	Aldron 70	70 mg	film coated tablets	Oral Use
PL - Poland	ICN Polfa Rezzarów S.A. Przemysłowa 2 35-959 Rzeszów, Poland	Alenato	10 mg	tablets	Oral Use
PL - Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego st. 11, 02-954 Warsaw, Poland	Alendran 70	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Orion Corporation Orionintie 1A, FI-02200 Espoo, Finland	Alendron	70 mg	tablets	Oral Use
PL - Poland	Generics [UK] Ltd. Station Close, Potters Bar, Hertfordshire, EN61TL, United Kingdom	Alendrogen	70 mg	tablets	Oral Use
PL - Poland	Sandoz GmbH Biochemiestrasse 10, A- 6250 Kundl, Austria	AlendroLek 70	70 mg	tablets	Oral Use
PL - Poland	Arrow Generics Ltd 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Alendromax 10 mg tabletki	10 mg	tablets	Oral Use
PL - Poland	Arrow Generics Ltd 2 Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom	Alendromax 70 mg tabletki	70 mg	tablets	Oral Use
PL - Poland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Alendronat Bluefish	70 mg/ tabl.	tablets	Oral Use
PL - Poland	PHARMABILL Jægersborg Alle 213 2 th DK-2820 Gentofte Denmark	Alendronat Pharmabill	70 mg	tablets	Oral Use
PL - Poland	ratiopharm GmbH Graf-Arco-Strasse 3, Ulm, 89073, Germany	Alendronat-ratiopharm 70	70 mg	tablets	Oral Use
PL - Poland	Arrow Poland S.A. Al. Jana Pawła II 23 00-854 Warsaw, Poland	Alendronate Arrow	10 mg	tablets	Oral Use
PL - Poland	Arrow Poland S.A. Al. Jana Pawła II 23 00-854 Warsaw, Poland	Alendronate Arrow	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Medana Pharma S.A. 10 Władysława Łokietka st., 98-200 Sieradz, Poland	Alendronate Medana	70 mg	tablets	Oral Use
PL - Poland	ACCORD HEALTHCARE LTD. Reg. Off.: Suite No. 10 & 11 Sage House 319 Pinner Road, North Harrow, Middlesex HA14HF, UK	Alendronate Sodium Accord	10 mg	tablets	Oral Use
PL - Poland	ACCORD HEALTHCARE LTD. Reg. Off.: Suite No. 10 & 11 Sage House 319 Pinner Road, North Harrow, Middlesex HA14HF, UK	Alendronate Sodium Accord	70 mg	tablets	Oral Use
PL - Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St., 00-113, Warsaw, Poland	Alendronate Teva	70 mg	tablets	Oral Use
PL - Poland	Farmacom Sp. z o.o. Mogilska 80 st. 31-546, Cracow, Poland	Alendronatum Farmacom	70 mg	tablets	Oral Use
PL - Poland	PLIVA Kraków Zakłady Farmaceutyczne S.A. ul. Mogilska 80 31-546 Cracow, Poland	Alenotop	10 mg	tablets	Oral Use
PL - Poland	Mepha Lda. Lagoas Park Edificio 5-A, Piso 2 2740-298 Porto Salvo Portugal	Densidron	70 mg	film coated tablets	Oral Use
PL - Poland	MSD Polska Sp. z o.o. Chłodna st., 51 00-867, Warsaw, Poland	Fosamax 70	70 mg	tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Phargem Sp. z o.o. Foksal St. 18/210/02 00-372 Warsaw, Poland	Kwas alendronowy 70 mg Tabletki	70 mg	tablets	Oral Use
PL - Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfirdi, Iceland	Lendrate	70 mg	tablets	Oral Use
PL - Poland	Zakłady Farmaceutyczne Polpharma SA Pelplińska st. 19 83-200 Starogard Gdański, Poland	Ostemax 70 comfort	70 mg	tablets	Oral Use
PL - Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St., 00-113, Warsaw, Poland	Ostenil	10 mg	tablets	Oral Use
PL - Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St., 00-113, Warsaw, Poland	Ostenil 70	70 mg	tablets	Oral Use
PL - Poland	Apotex Europe Ltd. Rowan House, 41 London Street, Reading Berkshire, RG1 4PS, United Kingdom	Ostodronic	70 mg	tablets	Oral Use
PL - Poland	Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o. Al. Jana Pawła II 80 00-175 Warsaw, Poland	Ostolek	10 mg	film coated tablets	Oral Use
PL - Poland	Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o. Al. Jana Pawła II 80 00-175 Warsaw, Poland	Ostolek	70 mg	film coated tablets	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Biofarm Sp. z o.o. Wałbrzyska 13, 60-198, Poznan, Poalnd	Rekostin 70 mg	70 mg	tablets	Oral Use
PL - Poland	Grodziskie Zakłady Farmaceutyczne "Polfa" Sp. z o.o Ks. J. Poniatowskiego st. 5 05-825 Grodzisk Mazowiecki, Poland	Sedron 70 mg tabletki powlekane	70 mg	film coated tablets	Oral Use
PT - Portugal	ISUS - Produtos Farmacêuticos e Cosméticos, S.A. Rua António Quadros, 9G - Escritório 3 1600-875 Lisboa Portugal	Ácido Alendróico Lendral	70 mg	Tablet	Oral Use
PT - Portugal	Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº 1499-016 Algés, Portugal	Ácido Alendróico Mylan	70 mg	Tablet	Oral Use
PT - Portugal	Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº 1499-016 Algés, Portugal	Ácido Alendróico Mylan	10 mg	Tablet	Oral Use
PT - Portugal	Premium Pharma - Sociedade Técnico Medicinal, Lda. Rua da Tapada Grande, n.º 2, Abrunheira, São Pedro de Penaferrim 2714-530 Sintra, Portugal	Ácido Alendróico Flamisul	70 mg	Film-coated Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Teva Pharma - Produtos Farmacêuticos, Lda. Edifício Cyprium, Av. 25 de Abril, 15, 2º F 2795-195 Linda-a-Velha Portugal	Ácido Alendrónico Teva	70 mg	Tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78 IS-220 Hafnarfjörour, Íslândia	Ácido Alendrónico Actavis	70 mg	Tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78 IS-220 Hafnarfjörour, Íslândia	Caldronate	70 mg	Tablet	Oral use
PT - Portugal	Almus, Lda. Rua Engenheiro Ferreira Dias, 772 4149-014 Porto	Ácido Alendrónico Almus	70 mg	Film-coated Tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto 2830 Coína, Portugal	Ácido Alendrónico Alter	70 mg	Tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto 2830 Coína, Portugal	Ácido Alendrónico Alter	10 mg	Tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto 2830 Coína, Portugal	Ácido Alendrónico Bifosal 10 mg Comprimidos	10 mg	Tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto 2830 Coína, Portugal	Ácido Alendrónico Bifosal 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	APceuticals - Farmacêutica, Lda.	Ácido Alendrónico Apceuticals	70 mg	Film-coated Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Apotex Europe, B.V. Darwinweg 20 2333 CR Leiden Netherland	Ácido Alendróico Apotex	70 mg	Tablet	Oral use
PT - Portugal	Arrowblue Produtos Farmacêuticos S.A. Av. D. João II, 10 Esqº - Torre Fernão de Magalhães 1998-025 Lisboa, Portugal	Ácido Alendróico Arrowblue 10 mg Comprimidos	10 mg	Tablet	Oral use
PT - Portugal	Arrowblue Produtos Farmacêuticos S.A. Av. D. João II, 10 Esqº - Torre Fernão de Magalhães 1998-025 Lisboa, Portugal	Ácido Alendróico Arrowblue 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Arrowblue Produtos Farmacêuticos S.A. Av. D. João II, 10 Esqº - Torre Fernão de Magalhães 1998-025 Lisboa, Portugal	Ácido Alendróico Winthrop 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Atlantic Pharma - Produções Farmacêuticas, S.A. Zona Industrial da Abrunheira, Rua da Tapada Grande, 2 2710-089 Sintra Portugal	Ácido Alendróico Blocan	70 mg	Film-coated Tablet	Oral use
PT - Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda. Av. do Forte, nº 3 - Parque Suécia, Edifício. IV, 2º 2794-038 Carnaxide, Portugal	Ácido Alendróico Glob	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Aurobindo Pharma (Portugal), Unipessoal Lda. Av. do Forte, nº 3 - Parque Suécia, Edifício. IV, 2º 2794-038 Carnaxide, Portugal	Ácido Alendróico Glob	10 mg	Tablet	Oral use
PT - Portugal	Baldacci - Portugal, S.A. Rua Cândido de Figueiredo, 84-B 1549-005 Lisboa, Portugal	Ácido Alendróico Nozat	70 mg	Film-coated Tablet	Oral use
PT - Portugal	Baldacci - Portugal, S.A. Rua Cândido de Figueiredo, 84-B 1549-005 Lisboa, Portugal	Ácido Alendróico Baldacci	70 mg	Tablet	Oral use
PT - Portugal	Biara - Produtos Farmacêuticos, Lda. Av. José Malhoa - Edifício Malhoa Plaza nº 2, piso- escritório 2.2 1070-325 Lisboa, Portugal	Ácido Alendróico Prella	70 mg	Tablet	Oral use
PT - Portugal	Bluepharma - Indústria Farmacêutica, S.A. São Martinho do Bispo Apartado 7003 3045-016 Coimbra, Portugal	Ácido Alendróico Bluepharma	70 mg	Tablet	Oral use
PT - Portugal	Ciclum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B 2770-229 Paço de Arcos, Portugal	Ácido Alendróico Ciclum 10 mg Comprimidos	10 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Cicum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B 2770-229 Paço de Arcos, Portugal	Ácido Alendróico Cicum 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Cinfa Portugal, Lda. Av. Tomás Ribeiro, 43 - Bloco 1, 4º B - Edifício Neopark 2790-221 Carnaxide, Portugal	Ácido alendróico Cinfa	70 mg	Tablet	Oral use
PT - Portugal	Daquimed - Comércio de Produtos Farmacêuticos, S.A. Av. Associação Comercial e Industrial de Gondomar, 330 - Zona Industrial da Portelinha 4510-688 Fânzeres, Portugal	Ácido Alendróico Daquimed	70 mg	Tablet	Oral use
PT - Portugal	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley HU17 OLD East Yorkshire, UK	Ácido Alendróico Dr. Reddy's	70 mg	Tablet	Oral use
PT - Portugal	Faribérica - Produtos Farmacêuticos, S.A. Estrada de Luz, 90 - 9º D/E 1600-160 Lisboa, Portugal	Ácido Alendróico Faribérica	70 mg	Tablet	Oral use
PT - Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra, Portugal	Ácido Alendróico Rinicas	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra, Portugal	Ácido Alendróico Farmoz	70 mg	Film-coated Tablet	Oral use
PT - Portugal	Frosst Portuguesa - Produtos Farmacêuticos, Lda. Quinta da Fonte - Edifício Vasco da Gama, 19 - Porto Salvo Apartado 214 2780-730 Paço D' Arcos, Portugal	Ácido Alendróico Frosst 70 mg	70 mg	Tablet	Oral use
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escritório 8 2710-444 Sintra, Portugal	Ácido Alendróico Generis 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide, Portugal	Ácido Alendróico Germed	70 mg	Tablet	Oral use
PT - Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide, Portugal	Ácido Alendróico Normon	70 mg	Tablet	Oral use
PT - Portugal	Helm Portugal, Lda. Estrada Nacional n.º 10, Km 140, 260 2695-066 Bobadela - Loures Portugal	Alehelm	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Helm Portugal, Lda. Estrada Nacional n.º 10, Km 140, 260 2695-066 Bobadela - Loures Portugal	Aleostito	70 mg	Tablet	Oral use
PT - Portugal	ITF Farma - Produtos Farmacêuticos, Lda. Rua Consiglieri Pedroso, 123 - Queluz de Baixo 2730-056 Barcarena, Portugal	Ácido Alendróico ITF	70 mg	Tablet	Oral use
PT - Portugal	Jaba Recordati, S. A. Lagoas Park, Edifício 5, Torre C, Piso 3 2740-298 Porto Salvo, Portugal	Ácido Alendróico Jaba 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros, Portugal	Ácido Alendróico Labesfal	10 mg	Tablet	Oral use
PT - Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros, Portugal	Ácido Alendróico Labesfal	70 mg	Tablet	Oral use
PT - Portugal	Laboratórios Anova - Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº 1499-016 Algés, Portugal	Ácido Alendróico Anova	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Laboratórios Anova - Produtos Farmacêuticos, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº 1499-016 Algés, Portugal	Ácido Alendrónico Laquifa	70 mg	Tablet	Oral use
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche, Portugal	Ácido Alendrónico Azevedos	70 mg	Tablet	Oral use
PT - Portugal	Laboratórios Basi - Indústria Farmacêutica, S.A. Rua do Padrão, 98 3000-312 Coimbra, Portugal	Ácido Alendrónico Basi	70 mg	Tablet	Oral use
PT - Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Lagoas Park, Edifício 5 A - Piso 2 2740-298 Porto Salvo, Portugal	Ácido Alendrónico Mepha 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Lagoas Park, Edifício 5 A - Piso 2 2740-298 Porto Salvo, Portugal	Ácido Alendrónico Stroban	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Mer Medicamentos, Lda. Office Park da Beloura, Edifício 4 - Piso 1 - Escritório 8, Quinta da Beloura 2710-444 Sintra, Portugal	Ácido Alendrónico Mer	70 mg	Tablet	Oral use
PT - Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte - Edifício Vasco da Gama, 19 - Porto Salvo Apartado 214 2770-192 Paço d' Arcos, Portugal	Fosamax	10 mg	Tablet	Oral use
PT - Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte - Edifício Vasco da Gama, 19 - Porto Salvo Apartado 214 2770-192 Paço d' Arcos, Portugal	Fosamax 70 mg	70 mg	Tablet	Oral use
PT - Portugal	Parke-Davis - Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo, Portugal	Ácido Alendrónico Parke-Davis	70 mg	Tablet	Oral use
PT - Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, Sala 31 1495-139 Miraflares - Algés, Portugal	Ácido Alendrónico Pharmakern	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, Sala 31 1495-139 Miraflares - Algés, Portugal	Ácido Alendróico GIDE	70 mg	Tablet	Oral use
PT - Portugal	Ranbaxy Portugal - Comércio e Desenvol. de Produtos Farmacêuticos, Unip., Lda. Rua do Campo Alegre, 1306, 3º - Sala 301/302 - Edifício Botânico 4150-174 Porto, Portugal	Ácido Alendróico Ranbaxy	70 mg	Tablet	Oral use
PT - Portugal	Ranbaxy Portugal - Comércio e Desenvol. de Produtos Farmacêuticos, Unip., Lda. Rua do Campo Alegre, 1306, 3º - Sala 301/302 - Edifício Botânico 4150-174 Porto, Portugal	Ácido Alendróico Alendrol	70 mg	Tablet	Oral use
PT - Portugal	Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda. Rua Quinta do Pinheiro - Edifício Tejo - 6º Piso 2790-143 Carnaxide, Portugal	Ácido Alendróico ratiopharm 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15 2710-693 Sintra Portugal	Ácido Alendróico Sandoz 70 mg Comprimidos	70 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15 2710-693 Sintra Portugal	Ácido Alendróico 1Apharma	70 mg	Tablet	Oral use
PT - Portugal	Sociedade J. Neves, Lda. Parque Industrial do Seixal 2840-068 Paio Pires, Portugal	Ácido Alendróico J. Neves 70 mg Comprimidos	70 mg	Tablet	Oral use
PT - Portugal	Tecnifar - Indústria Técnica Farmacêutica, S.A. Rua Tierno Galvan - Amoreiras - Torre 3 - 12º 1099-036 Lisboa, Portugal	Adronat	10 mg	Tablet	Oral use
PT - Portugal	Tecnifar - Indústria Técnica Farmacêutica, S.A. Rua Tierno Galvan - Amoreiras - Torre 3 - 12º 1099-036 Lisboa, Portugal	Adronat 70 mg	70 mg	Tablet	Oral use
PT - Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 - Abrunheira 2710-089 Sintra Portugal	Ácido Alendróico Ecosis 70 mg Comprimidos	70 mg	Film-coated Tablet	Oral use
PT - Portugal	Tetrafarma - Produtos Farmacêuticos, Lda. Rua Helena Aragão, 20 R/C Frente - Massamá 2745-879 Queluz, Portugal	Ácido Alendróico Tetrafarma	70 mg	Film-coated Tablet	Oral use
PT - Portugal	ToLife - Produtos Farmacêuticos, S.A. Avenida do Forte, 3 - Edifício Suécia III, Piso 1 2794-093 Carnaxide, Portugal	Ácido Alendróico ToLife 70 mg Comprimidos	70 mg	Film-coated Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Verum Pharma - Produtos Farmacêuticos - Unipessoal, Lda Av. Sidónio Pais, n.º 24, rés-do-chão esq, São Sebastião da Pedreira 1000 Lisboa, Portugal	Ácido Alendrónico Flazium	70 mg	Film-coated Tablet	Oral Use
RO - Romania	MERCK SHARP & DOHME ROMÂNIA S.R.L.Bucharest Business ParkŞos. Bucureşti-Ploieşti, Nr. 1A,Clădirea C1, Etaj 3,Sector 1, Bucureşti, România	FOSAMAX 5mg	5 mg	Tablet	Oral Use
RO - Romania	MERCK SHARP & DOHME ROMÂNIA S.R.L.Bucharest Business ParkŞos. Bucureşti-Ploieşti, Nr. 1A,Clădirea C1, Etaj 3,Sector 1, Bucureşti, România	FOSAMAX 10mg	10 mg	Tablet	Oral Use
RO - Romania	MERCK SHARP & DOHME ROMÂNIA S.R.L.Bucharest Business ParkŞos. Bucureşti-Ploieşti, Nr. 1A,Clădirea C1, Etaj 3,Sector 1, Bucureşti, România	FOSAMAX 70mg	70 mg	Tablet	Oral Use
RO - Romania	S.C. TEVA PHARMACEUTICALS S.R.L.,Str. Domnița Ruxandra nr. 12, Parter, Sectorul 2, Bucureşti, România	TEVANAT 10mg	10 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
RO - Romania	S.C. TEVA PHARMACEUTICALS S.R.L., Str. Domnița Ruxandra nr. 12, Parter, Sectorul 2, București, România	TEVANAT 70mg	70 mg	Tablet	Oral Use
RO - Romania	SANDOZ S.R.L. , Str. Livezeni nr. 7A, Târgu Mureș, România	ALENDRONAT SANDOZ	70 mg	film coatet tablet	Oral Use
RO - Romania	GEDEON RICHTER ROMÂNIA S.A. , România	SEDRON	70 mg	film coatet tablet	Oral Use
RO - Romania	ACCORD HEALTHCARE LIMITED, Sage house, 319 Pinner road, North Harrow HA1 4 HF, Middlesex, Marea Britanie	ACID ALENDRONIC ACCORD10mg	10 mg	Tablet	Oral Use
RO - Romania	ACCORD HEALTHCARE LIMITED, Sage house, 319 Pinner road, North Harrow HA1 4 HF, Middlesex, Marea Britanie	ACID ALENDRONIC ACCORD 70mg	70 mg	Tablet	Oral Use
RO - Romania	TERAPIA SA, Str. Fabricii nr. 124, Cluj Napoca, România	RANOS 10mg	10 mg	Tablet	Oral Use
RO - Romania	TERAPIA SA, Str. Fabricii nr. 124, Cluj Napoca, România	RANOS 70mg	70 mg	Tablet	Oral Use
RO - Romania	LABORATOARELE PROF. Dr. MORAIT, Str. Sperantei nr.29, Bucuresti sector 2, Romania	ANDRONIK	70 mg	film coatet tablet	Oral Use
RO - Romania	BLUEFISH PHARMACEUTICALS AB, Torsgatan 11, 111 23 Stockholm, Sweden	ACID ALENDRONIC BLUEFISH	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
RO - Romania	PHARMACEUTICAL WORKS POLPHARMA SA,19 Pelplińska Street, 83-200 Starogard Gdański, Polonia	OSTEMAX	70 mg	Tablet	Oral Use
RO - Romania	Dr. REDDY'S LABORATORIES , Str. Av. Petre Crețu nr. 74, et. 1, ap. 2, sect. 1, București, România	INSTREL	70 mg	Tablet	Oral Use
RO - Romania	Teva Pharmaceuticals S.R.L, Str Domnita Ruxandra nr. 12, parter, sector 2, 020562, Bucuresti Romania	Teva nat, 70 mg comprimat	70mg	Tablet	Oral Use
SE - Sweden	Merck Sharp & Dohme BV, PO Box 581, NL-2003 PC Harlem, Netherlands (NLD)	Fosamax	10 mg	tablet	Oral Use
SE - Sweden	Merck Sharp & Dohme BV, PO Box 581, NL-2003 PC Harlem, Netherlands (NLD)	Fosamax veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alendronate Arrow	10 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alendronate Arrow veckotablett	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alenat	10 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alenat veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Medarin	10 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Medarin veckotablett	70 mg	tablet	Oral Use
SE - Sweden	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Dedarin veckotablett	70 mg	tablet	Oral Use
SE - Sweden	CT Arzneimittel GmbH, Lengeder Strasse 42 a, DE- 13407 Berlin, Germany	Gendarin veckotablett	70 mg	tablet	Oral Use
SE - Sweden	PLIVA Pharma Ltd, Vision House, Bedford Road, Petersfield Hampshire, GU32 3QB, United Kingdom and Northern Ireland	Kendarin	10 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	PLIVA Pharma Ltd, Vision House, Bedford Road, Petersfield Hampshire, GU32 3QB, United Kingdom and Northern Ireland	Kendarin veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alendroarrow	10 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	Alendroarrow veckotablett	70 mg	tablet	Oral Use
SE - Sweden	ratiopharm GmbH, Graf-Arco-Strasse 3, DE-89079 Ulm, Germany	Alendronat ratiopharm veckotablett	70 mg	tablet	Oral Use
SE - Sweden	STADA Arzneimittel AG, Stadastrasse 2-18, DE-61118 Bad Vilbel, Germany (DEU)	Alendrostad	10 mg	tablet	Oral Use
SE - Sweden	STADA Arzneimittel AG, Stadastrasse 2-18, DE-61118 Bad Vilbel, Germany (DEU)	Alendrostad veckotablett	70 mg	tablet	Oral Use
SE - Sweden	STADA Arzneimittel AG, Stadastrasse 2-18, DE-61118 Bad Vilbel, Germany (DEU)	Alendronat STADA	10 mg	tablet	Oral Use
SE - Sweden	STADA Arzneimittel AG, Stadastrasse 2-18, DE-61118 Bad Vilbel, Germany (DEU)	Alendronat STADA veckotablett	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Interpharm ProduktionsgmbH, Effingerstrasse 21, AT-1160 Wien, Austria (AUT)	Alendronat Interpharm	10 mg	tablet	Oral Use
SE - Sweden	Interpharm ProduktionsgmbH, Effingerstrasse 21, AT-1160 Wien, Austria (AUT)	Alendronat Interpharm veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Hexal A/S Kanalholmen 8-12 DK-2650 Hvidovre Denmark	Alendronat Hexal	10 mg	tablet	Oral Use
SE - Sweden	Hexal A/S Kanalholmen 8-12 DK-2650 Hvidovre Denmark	Alendronat Hexal Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	AlendroLich	10 mg	tablet	Oral Use
SE - Sweden	Arrow Generics Ltd, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom and Northern Ireland (GBR)	AlendroLich Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Alendronat Orifarm Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Mylan AB Box 23033 104 35 Stockholm Sweden	Alendronat Mylan Veckotablett	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. PL-83-200 Starogard Gdanski Poland	Alendropol Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. PL-83-200 Starogard Gdanski Poland	Alendrixen Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. PL-83-200 Starogard Gdanski Poland	Polerixen Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	HELP S.A. Pharmaceuticals 10, Valaoritou Str. Metamorphosis 144 52 Athen Greece	Terixen Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. PL-83-200 Starogard Gdanski Poland	Alenpol Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Pharmaceutical Works Polpharma S.A. 19 Pelplinska Str. PL-83-200 Starogard Gdanski Poland	Alendronat Polpharma Veckotablett	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Ranbaxy (UK) Ltd 20 Balderton Street London W1K 6TL United Kingdom	Alendronat Ranbaxy Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Mylan AB Box 23033 104 35 Stockholm Sweden	Alendronat Mylan	10 mg	tablet	Oral Use
SE - Sweden	Sandoz A/S C.F. Tietgens Boulevard 40 DK-5220 Odense SØ Denmark	Alendronat Sandoz Veckotablett	70 mg	film-coated tablet	Oral Use
SE - Sweden	Hexal A/S Kanalholmen 8-12 DK-2650 Hvidovre Denmark	Alendronat Hexal Veckotablett	70 mg	film-coated tablet	Oral Use
SE - Sweden	1A Farma A/S Herstedøstervej 27-29 DK-2620 Albertslund Denmark	Alendronat 1A Farma Veckotablett	70 mg	film-coated tablet	Oral Use
SE - Sweden	Accord Healthcare Limited Sage House 319 Pinner Road North Harrow, Middlesex HA1 4HF United Kingdom	Alendronat Accord	10 mg	tablet	Oral Use
SE - Sweden	Accord Healthcare Limited Sage House 319 Pinner Road North Harrow, Middlesex HA1 4HF United Kingdom	Alendronat Accord Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 111 23 Stockholm Sweden	Alendronat Bluefish Veckotablett	70 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Actavis Group PTC ehf. Reykjavíkurvegur 76-78 IS-220 Hafnarfjörður Island	Alendronat Actavis Veckotablett	70 mg	tablet	Oral Use
SE - Sweden	Orion Corporation, Orion Pharma PO Box 65 FI-02101 Espoo Finland	Alendronat Orion Veckotablett	70 mg	tablet	Oral Use
SI - Slovenia	Generics UK Ltd., Station Close, Potters Bar, Hertford Shire EN6 1AG, UK	Alenax 70 mg tablete	70 mg	tablet	Oral Use
SI - Slovenia	Pliva Ljubljana d.o.o., pot k sejmišču 35, SI-1231 Ljubljana- Črnuče, Slovenia	Alendor 70 mg tablete	70 mg	tablet	Oral Use
SI - Slovenia	Arrow Generics Limited, 2 Eastman Way, Stevenage, Hertfordshire, UK	Alendronat Arrow 10 mg	10 mg	tablet	Oral Use
SI - Slovenia	Arrow Generics Limited, 2 Eastman Way, Stevenage, Hertfordshire, UK	Alendronat Arrow 70 mg	70 mg	tablet	Oral Use
SI - Slovenia	Lek farmacevtska družba, d.d., Verovškova 57, SI- 1000 Ljubljana, Slovenia	Alendronat Lek 70 mg filmsko obložene tablete	70 mg	film-coated tablet	Oral Use
SI - Slovenia	Kemofarmacija d.d., cesta na Brdo 100, SI-1000 Ljubljana Slovenia	Forosa 70 mg filmsko obložene tablete	70 mg	film-coated tablet	Oral Use
SI - Slovenia	Merck Sharp& Dohme, inovativna zdravila d.o.o., Šmartinska cesta 140, SI- 1000 Ljubljana	Fosamax enkrat tedensko 70 mg tablete	70 mg	tablet	Oral Use
SI - Slovenia	Krka, tovarna zdravil, d.d., Šmarješka cesta 6, SI-8501 Novo mesto, Slovenia	Lindron 10 mg tablete	10 mg	tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SI - Slovenia	Actavis Group PTC ehf., Reykjavíkurvegi 78, 220 Hafnarfjörður, Iceland	Natrijev alendronat Actavis 70 mg tablete	70 mg	tablet	Oral Use
SI - Slovenia	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, NL	Tevanate 70 mg tablete	70 mg	tablet	Oral Use
SK - Slovakia	Merck Sharp & Dohme B.V. Waarderweg 39 P.O. Box 581, Haarlem, 2031 BN Netherlands	FOSAMAX 70 mg 1 x týždenne	70 mg	Tablet	Oral Use
SK - Slovakia	Bentley Pharmaceuticals Ireland Limited North Wall Quay 25 - 28 Dublin 1 Ireland	Gendron 70 Tablety	70 mg	Tablet	Oral Use
SK - Slovakia	Teva Pharmaceuticals CR , s.r.o. Radlická 3185/1c 150 00 Praha 5 Czech Republic	Tevalen 70 mg	70 mg	Tablet	Oral Use
SK - Slovakia	Gedeon Richter Plc. Gyômrői út 19-21 1103, Budapest Hungary	Siranin 70 mg filmom obalené tablety	70 mg	Film coated tablet	Oral Use
SK - Slovakia	Generics (UK) Ltd. Station Close, Hertfordshire Potters Bar, EN6 1TL United Kingdom	Alendrogen 70 mg	70 mg	Tablet	Oral Use
SK - Slovakia	Arrow Generics Limited Unit 2, Eastman Way, Stevenage, Hertfordshire, SG14SZ United Kingdom	Alendromax 70 mg tablety	70 mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SK - Slovakia	ratiopharm GmbH Graf-Arco-Strasse 3 Ulm, 89079 Germany	Alendronat-ratiopharm 70 mg	70 mg	Tablet	Oral Use
SK - Slovakia	Sandoz Pharmaceuticals d.d. Verovškova 57, Ljubljana 1000 Slovenia	Alendronát Sandoz 70 mg 1 x týždenne tablety	70 mg	Tablet	Oral Use
SK - Slovakia	Xeolas Pharmaceuticals Limited 97 Furry Park Road Killester, Dublin 5 Ireland	Bonasol 70 mg perorálny roztok	70 mg	Oral Solution	Oral Use
SK - Slovakia	Actavis Group PTC ehf; Reykjavíkurvegi 76-78, 220 Hafnarfjörður Iceland	Alendronat Actavis	70 mg	tablets	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Fosamax	10mg	Tablet	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Fosamax Once weekly	70mg	Tablet	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Adronat Once weekly	70mg	Tablet	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Alegen Once weekly	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Alendros Once Weekly	70mg	Tablet	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Once weekly	70mg	Tablet	Oral Use
UK - United Kingdom	MERCK SHARP & DOHME LIMITED Hertford Road, Hoddesdon, Hertfordshire EN11 UK	Fosatrol Once weekly	70mg	Tablet	Oral Use
UK - United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Sandoz Limited, 37 Woolmer Way, Bordon, Hampshire GU35 9QE	alendronic acid	70mg	Film-coated tablet	Oral Use
UK - United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL	alendronic acid	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Gideon Richter Plc, Gyomrui Utca 19-21, Budapest H-1103, Hungary	alendronic acid	70mg	Film-coated tablet	Oral Use
UK - United Kingdom	Gideon Richter Plc, Gyomrui Utca 19-21, Budapest H-1103, Hungary	alendronic acid	70mg	Film-coated tablet	Oral Use
UK - United Kingdom	Dr Reddy's Laboratories (UK) Limited, 6 Riverview Road, Beverley, East Yorkshire HU17 0LD, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Pliva Pharma Limited, Vision House, Bedford Road, Petersfield, Hampshire GU23 3QB, United Kingdom	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Pliva Pharma Limited, Vision House, Bedford Road, Petersfield, Hampshire GU23 3QB, United Kingdom	alendronic acid once-weekly	70mg	Tablet	Oral Use
UK - United Kingdom	Ranbaxy (UK) Limited, 95 Park Lane, Mayfair. London W1K 7TE, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Strandhaven Limited, 600 High Road, Seven Kings, Ilford, Essex IG3 8BS, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Ratiopharm GmbH, 5 Jackson Close, Grove Road, Cosham, Portsmouth, Hampshire, PO6 1UP	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Prostrakan Limited, 3 Galabank Business Park, Queen Street, Galashiels, TD1 1QH, United Kingdom	Ostalis	70mg	Film-coated tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS, United Kingdom	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Arrow Generics Limited, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Arrow Generics Limited, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Accord Healthcare Limited, Sage House, 319 Pinner Road, Harrow, Middlesex HA1 4HF, United Kingdom	alendronic acid	10mg	Tablet	Oral Use
UK - United Kingdom	Accord Healthcare Limited, Sage House, 319 Pinner Road, Harrow, Middlesex HA1 4HF, United Kingdom	alendronic acid once weekly	70mg	Tablet	Oral Use
UK - United Kingdom	Accord Healthcare Limited, Sage House, 319 Pinner Road, Harrow, Middlesex HA1 4HF, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Relonchem Limited, 27 Old Gloucester Street, London WC1 3XX, United Kingdom	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Resource Medical (UK) Limited, 2 Carlton Avenue, Batley, West Yorkshire WF17 7AQ, United Kingdom	alendronic acid	70mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Laboratorios Davur S.L., Calle Teide 4. Parque Empresarial La Marina, 28700 San Sebastian De Los Reyes, Madrid E-28700 Spain	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Apotex Europe BV, Darwinweg 20, Leiden, NL 2333 CR, Netherlands	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Wockhardt UK Limited, Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, UK	alendronic acid	70mg	Tablet	Oral Use
UK - United Kingdom	Actavis Group PTC EHF, Reykjavikurvegi 76-78, Hafnarfirdi IS-220 Iceland	alendronic acid	70mg	Tablet	Oral Use

Clodronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Bayer Austria Ges.m.b.H. Herbststraße 6 – 10 A-1160 Wien, Austria	Bonefos 800 mg - Filmdtabletten	800 mg (Clodronate Disodium)	film-coated tablet	Oral use
AT - Austria	Bayer Austria Ges.m.b.H. Herbststraße 6 – 10 A-1160 Wien, Austria	Bonefos 300 mg - Konzentrat zur Infusionsbereitung	300 mg/5 ml (Clodronate Disodium)	concentrate for solution for infusion	Intravenous
AT - Austria	Roche Austria GmbH, Engelhorngasse 3, A-1211 Wien, Austria	Lodronat 520 mg - Filmdtabletten	520 mg (Clodronate Disodium)	film-coated tablet	Oral use
BE - Belgium	Bayer SA.NV. J.E. Mommaertslaen 14 1831 Diegem-Machelen Belgium	Bonefos	300 mg/5 ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Bayer SA.NV. J.E. Mommaertslaen 14 1831 Diegem-Machelen Belgium	Bonefos	800 mg	Film-coated tablets	Oral use
BG - Bulgaria	Atavis EAD 1407 Sofia 29 Atanas Dukov Str. Bulgaria	Sindronat	400 mg	capsules, hard	Oral use
CZ - Czech Republic	Bayer Schering Pharma Oy PO Box 415, FI-20101 Turku, Finland	Bonefos	60mg/1ml	Concentrate for solution for infusion	Infusion

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Bayer Schering Pharma Oy PO Box 415, FI-20101 Turku, Finland	Bonefos 400mg	400mg	Capsule, hard	Oral use
CZ - Czech Republic	Bayer Schering Pharma Oy PO Box 415, FI-20101 Turku, Finland	Bonefos 800mg	800mg	Film-coated tablet	Oral use
CZ - Czech Republic	Roche s.r.o., Dukelských hrdinů 567/52, 170 00 Praha-Holešovice, Czech Republic	Lodronat 520	520mg	Film-coated tablet	Oral use
DE - Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching	Clodron 800-1 A Pharma	1000 mg	Film-coated tablet	Oral use
DE - Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching	Clodron 400-1 A Pharma	500 mg	Film-coated tablet	Oral use
DE - Germany	Bayer Vital GmbH Kaiser-Wilhelm-Allee D-51373 Leverkusen	Bonefos pro infusione	75 mg	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Bayer Vital GmbH Kaiser-Wilhelm-Allee D-51373 Leverkusen	Bonefos	500 mg	Capsule, hard	Oral use
DE - Germany	Bayer Vital GmbH Kaiser-Wilhelm-Allee D-51373 Leverkusen	BONEFOS FILMTABLETTEN 800mg	1000 mg	Film-coated tablet	Oral use
DE - Germany	betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg	Clodron beta 800mg	1000 mg	Film-coated tablet	Oral use
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Clodron HEXAL PI	374,9 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Clodron 800 mg HEXAL Filmtabletten	1000 mg	Film-coated tablet	Oral use
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Clodron 800 mg HEXAL Filmtabletten	500 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Roche Pharma AG Emil-Barell-Str. 1 D-79639 Grenzach-Wyhlen	Ostac	649,73 mg	Film-coated tablet	Oral use
DE - Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen	Clodron Sandoz 300 mg Konzentrat zur Herstellung einer Infusionslösung	300 mg	Concentrate for solution for infusion	Intravenous
DK - Denmark	Bayer AB, Postbox 606, Gustav III:s Boulevard 56, SE-16926 Solna	Bonefos	800 mg	film-coated tablets	Oral use
ES - Spain	QUIMICA FARMACEUTICA BAYER, S.L.Av. Baix Llobregat, 3-5 08970 Sant Joan Despi	BONEFOS 400 mg cápsulas	400 mg	capsules	Oral use
ET - Estonia	Bayer Schering Pharma OY Pansiontie 47 20210 Turku FINLAND	BONEFOS	800mg	Film-coated tablet	Oral use
ET - Estonia	Bayer Schering Pharma OY Pansiontie 47 20210 Turku FINLAND	BONEFOS	400mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ET - Estonia	Bayer Schering Pharma OY Pansiontie 47 20210 Turku FINLAND	BONEFOS	60mg 1 ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	60 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	400 mg	capsule, hard	Oral use
FI - Finland	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	800 mg	film-coated tablet	Oral use
FI - Finland	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Clodrobon	400 mg	capsule, hard	Oral use
FI - Finland	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Clodrobon	800 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	BAYER SANTE 220, avenue de la Recherche 59120 Loos FRANCE	CLASTOBAN 300 mg/5 ml, solution injectable pour perfusion en ampoule	300 mg/5 ml	solution	Intravenous
FR - France	BAYER SANTE 220, avenue de la Recherche 59120 Loos FRANCE	CLASTOBAN 400 mg, gélule	400 mg	capsule	Oral use
FR - France	BAYER SANTE 220, avenue de la Recherche 59120 Loos FRANCE	CLASTOBAN 800 mg, gélule	800 mg	tablet	Oral use
FR - France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	CLODRONATE DE SODIUM G GAM 400 mg, comprimé enrobé	400 mg	tablet	Oral use
FR - France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	CLODRONATE DE SODIUM G GAM 800 mg, comprimé pelliculé	800 mg	tablet	Oral use
FR - France	ROCHE 52, boulevard du Parc 92521 Neuilly-sur-Seine Cedex FRANCE	LYTOS 520 mg, comprimé pelliculé	520 mg	tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Bayer Schering Pharma Oy Pansiontie 47. 20210 Turku Finland	BONEFOS 800 mg tabletta	800 mg Disodium clodronate anhydrous (in the form of 1000 mg Disodium clodronate tetrahydrate	tablet	Oral use
HU - Hungary	Bayer Schering Pharma Oy Pansiontie 47. 20210 Turku Finland	BONEFOS 400 mg kemény kapszula	400 mg Disodium clodronate anhydrous (in the form of 500 mg Disodium clodronate tetrahydrate	hard capsules	Oral use
HU - Hungary	Bayer Schering Pharma Oy Pansiontie 47. 20210 Turku Finland	BONEFOS 60 mg/ml koncentrátum oldatos infúzióhoz	60 mg/ml Disodium clodronate anhydrous (in the form Disodium clodronate tetrahydrate	concentrate for solution for infusion	Parenteral
IE - Ireland	Bayer Limited The Atrium Blackthorn Road Dublin 18	Bonefos 800 mg film- coated tablets.	800 mg	Film-coated tablets	Oral use
IS - Iceland	Bayer Ab, Box 606, Solna, Sweden	Bonefos	800 mg	Tablet	Oral use
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	CLASTEON	100 mg/3,3 ml	Solution for injection	Intramuscular

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	FIDIA FARMACEUTICI SpA Via Ponte Della Fabbrica, 3/A - 35031 Abano Terme (PD)	CLODRON	100 mg/3,3 ml	Solution for injection	Intramuscular
IT - Italy	PROMEDICA Srl Via Palermo, 26/A - 43100 Parma	CLODY	100 mg/3,3 ml	Solution for injection	Intramuscular
IT - Italy	SPA - SOCIETA' PRODOTTI ANTIBIOTICI SpA Via Biella, 8 20143 Milano	DIFOSFONAL	100 mg/3,3 ml	Solution for injection	Intramuscular
IT - Italy	ISTITUTO BIOCHIMICO NAZIONALE SAVIO SRL Via E. Bazzano, 14 16019 Ronco Scrivia - Genova (Italy)	NIKLOD	100 mg/3,3 ml	Solution for injection	Intramuscular
IT - Italy	ABC FARMACEUTICI SpA Corso Vittorio Emanuele II, 72 10121 Torino	CLODRONATO ABC	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	ABC FARMACEUTICI SpA Corso Vittorio Emanuele II, 72 10121 Torino	CLODRONATO ABC	300 mg/10 ml	Solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	CLASTEON	300 mg	Concentrate for solution for infusion	Intravenous
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	CLASTEON	400 mg	Capsule, hard	Oral Use
IT - Italy	EG SpA Via Pavia, 6 - 20136 Milano - Italy	ACIDO CLODRONICO EG	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	FARMACEUTICI CABER SpA Viale Città d' Europa, 681 00144 Roma	OSTEONORM	100 mg	Solution for injection	Intramuscular, Intravenous
IT - Italy	FIDIA FARMACEUTICI SpA Via Ponte Della Fabbrica, 3/A - 35031 Abano Terme (PD)	CLODRON	300 mg/10 ml	Solution for injection	Intravenous
IT - Italy	FIDIA FARMACEUTICI SpA Via Ponte Della Fabbrica, 3/A - 35031 Abano Terme (PD)	CLODRON	400 mg	Capsule	Oral Use
IT - Italy	ISTITUTO BIOCHIMICO NAZIONALE SAVIO SRL Via E. Bazzano, 14 16019 Ronco Scrivia - Genova (Italy)	NIKLOD	300 mg/10 ml	Concentrate for solution for infusion	Intravenous
IT - Italy	LABORATORI ALTER Srl Via Lomellina, 39 - 20124 Milano	DISODIO CLODRONATO ALTER	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	LABORATORI ALTER Srl Via Lomellina, 39 - 20124 Milano	DISODIO CLODRONATO ALTER	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	LISAPHARMA SpA Via Licinio, 11 22036 Erba (CO)	MOTICLOD	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	LISAPHARMA SpA Via Licinio, 11 22036 Erba (CO)	MOTICLOD	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	MASTELLI Srl Via Bussana Vecchia, 32 18032 San Remo (IM)	CLIMACLOD	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	MASTELLI Srl Via Bussana Vecchia, 32 18032 San Remo (IM)	CLIMACLOD	100 mg/3,3 ml	Solution for injection	Intramuscular
IT - Italy	MYLAN SpA Via Aquileia, 35 - 20092 Cinisello Balsamo Milano	ACIDO CLODRONICO MYLAN GENERICS	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	MYLAN SpA Via Vittor Pisani, 20 - 20124 Milano	ACIDO CLODRONICO MYLAN GENERICS	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	PROMEDICA Srl Via Palermo, 26/A - 43100 Parma	CLODY	300 mg/10 ml	Concentrate for solution for infusion	Intravenous
IT - Italy	ROTTAPHARM SpA Via Galleria Unione,5 20122 Milano (MI)	OSTEOTAB	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	ROTTAPHARM SpA Via Galleria Unione,5 20122 Milano (MI)	OSTEOTAB	300 mg/10 ml	Solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	SANDOZ SpA L.go U. Boccioni, 1 - 21040 Origgio (VA)	ACIDO CLODRONICO	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	SANDOZ SpA L.go U. Boccioni, 1 - 21040 Origgio (VA)	ACIDO CLODRONICO	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	SPA - SOCIETA' PRODOTTI ANTIBIOTICI SpA Via Biella, 8 20143 Milano	DIFOSFONAL	300 mg/10 ml	Concentrate for solution for infusion	Intravenous
IT - Italy	SPA - SOCIETA' PRODOTTI ANTIBIOTICI SpA Via Biella, 8 20143 Milano	DIFOSFONAL	400 mg	Capsule	Oral Use
IT - Italy	TEVA ITALIA Srl Via Messina, 38 - 20154 Milano - Italy	CLODRONATO TEVA	100 mg/3,3 ml	Solution for injection	Intramuscular, Intravenous
IT - Italy	TEVA ITALIA Srl Via Messina, 38 - 20154 Milano	CLODRONATO TEVA	300 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	LABORATORIO PRODOTTI FARMACEUTICI BONISCONTRO & GAZZONE Srl Via Pavia, 6 - 20136 Milano - Italy	CLODEOSTEN	100 mg/3,3 ml	Solution for injection	Intravenous
IT - Italy	ATHENA PHARMA ITALIA SRL Viale Citta D'Europa, 681 00144 Roma	TRAXOVICAL	100 mg/3,3 ml	Solution for injection	Intravenous
IT - Italy	ATHENA PHARMA ITALIA SRL Viale Citta D'Europa, 681 00144 Roma	TRAXOVICAL	300 mg/10 ml	Solution for infusion	Intravenous
LU - Luxembourg	Bayer s.a. 14, J.E. Mommaertslaan B-1831 Diegem	Bonefos	300 mg/5ml	solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LV - Latvia	Bayer Schering Pharma Oy, Pansiontie 47, FIN-20210 Turku, Finland	Bonefos	60 mg/ml	concentrate for solution for infusion	Intravenous
LV - Latvia	Bayer Schering Pharma Oy, Pansiontie 47, FIN-20210 Turku, Finland	Bonefos	400 mg	capsules	Oral use
MT - Malta	Bayer plc Consumer Care Division Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	Bonefos	400mg	Capsules	Oral use
NL - Netherlands	Roche Nederland B.V. Beneluxlaan 2a 3446 GR Woerden Netherlands	Ostac, concentration for solution for infusion 30 mg/ml	30 mg/ml	concentration for solution for infusion	Intravenous
NL - Netherlands	Roche Nederland B.V. Beneluxlaan 2a 3446 GR Woerden Netherlands	Ostac® 520, filmcoated tablets 520 mg	520 mg	filmcoated tablets	Oral use
NL - Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht	Bonefos	60 mg/ml	concentration for solution for infusion	Intravenous
NL - Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht	Bonefos capsules 400 mg	400 mg	hard capsules	Oral use
NL - Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht	Bonefos tablets 800 mg	800 mg	filmcoated tablets	Oral use
NO - Norway	Bayer AB Box 606 169 26 Solna Sweden	Bonefos	800 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Bayer Schering Pharma AG Berlin, D-13342, Germany	Bonefos	400 mg	capsules, hard	Oral use
PL - Poland	Bayer Schering Pharma AG Berlin, D-13342, Germany	Bonefos	60 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	Bayer Schering Pharma AG Berlin, D-13342, Germany	Bonefos	800 mg	film coated tablets	Oral use
PL - Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfirdi, Iceland	Sindronat	400 mg	capsules, hard	Oral use
PT - Portugal	Roche Farmacêutica Química, Lda. Estrada Nacional 249, 1, 2720-413 Amadora Portugal	Ostac	520 mg	Coated tablet	Oral use
PT - Portugal	Lusalfarma - Especialidades Farmacêuticas, Lda. Rua Quinta Pinheiro, 5, Outurela 2794-003 Carnaxide Portugal	Bonefos	800 mg	Film-coated tablet	Oral use
RO - Romania	BAYER SCHERING PHARMA OY, Pansiontie 47, 20210 Turku, Finland	BONEFOS 400 mg, capsules	400 mg	capsules	Oral use
RO - Romania	BAYER SCHERING PHARMA OY, Pansiontie 47, 20210 Turku, Finland	BONEFOS 800 mg, capsules	800 mg	capsules	Oral use
RO - Romania	BAYER SCHERING PHARMA OY, Pansiontie 47, 20210 Turku, Finland	BONEFOS 60 mg/ml concentrate for solution for infusion	60 mg/ml	concentrate for solution for infusion	Parenteral
RO - Romania	ACTAVIS S.R.L. B-dul Ion Mihalache, nr. 11 Sector 1, Cod 011171, București, Romania	SINDRONAT 300 mg/5 ml concentrate for solution for infusion	300 mg/5 ml	concentrate for solution for infusion	Prenteral

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Bayer AB Box 606 169 26 Solna Sweden	Bonefos	60 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	Bayer AB Box 606 169 26 Solna Sweden	Bonefos	800 mg	film-coated tablet	Oral use
SI - Slovenia	Bayer Schering Pharma Oy, Pansiontie 47, 20210 Turku, Finland	Bonefos 60 mg/ml koncentrat za raztopine za infundiranje	60 mg/ml	concentrate for solution for infusion	Intravenous
SI - Slovenia	Bayer Schering Pharma Oy, Pansiontie 47, 20210 Turku, Finland	Bonefos 800 mg filmsko obložene tablete	800 mg	film-coated tablet	Oral use
SK - Slovak Republic	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	60 mg/ml	Concentrate for solution for infusion	Intravenous
SK - Slovak Republic	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	400 mg	capsule, hard	Oral use
SK - Slovak Republic	Bayer Schering Pharma Oy, Pansiontie 47, PL 415, 20210 Turku, Finland	Bonefos	800 mg	film-coated tablet	Oral use
UK - United Kingdom	Bayer Plc, bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK	Bonefos	400 mg	Capsules	Oral use
UK - United Kingdom	Bayer Plc, bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK	Bonefos	800 mg	coated Tablets	Oral use
UK - United Kingdom	Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, UK	Loron 540		film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Beacon Pharmaceuticals Limited, 85, High street, Tunbridge Wells, TN1 1YG, UK	Clasteon	400 mg	Capsules	Oral use
UK - United Kingdom	Beacon Pharmaceuticals Limited, 85, High street, Tunbridge Wells, TN1 1YG, UK	Sodium clodronate	400mg	Capsules	Oral use
UK - United Kingdom	Caduceus Pharma Limited, 6th floor, 94 Wigmore Street, London W1U 3RF, UK	Disodium Clodronate	60mg/ml	solution for Injection	Intravenous

Etidronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Procter & Gamble Pharmaceuticals SA.NV. Temselaan 100	Didronel	200 mg	Tablets	Oral use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Osteodidronel	400 mg	Tablets	Oral use
DE - Germany	mibe GmbH Arzneimittel Münchener Str. 15 D-06796 Brehna	Etidronat 200 mg Jenapharm	200 mg	Tablet	Oral use
DE - Germany	C.H.R. Heim Arzneimittel GmbH Elisabethenstr. 34 D-64283 Darmstadt	Etical	400 mg 1250 mg	Tablet	Oral use
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Etidron HEXAL Kombi	400 mg 1250 mg	Tablet and effervescent tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Didronel-Kit	400 mg 1250 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Procter & Gamble Pharmaceuticals UK Ltd., Rusham Park Technical Centre, Whitehall Lane, GB- TW20 9 NW Egham, Surrey, England	Didronate	200 mg	Tablets	Oral use
DK - Denmark	Procter & Gamble Pharmaceuticals UK Ltd., Rusham Park Technical Centre, Whitehall Lane, GB- TW20 9 NW Egham, Surrey, England	Didronate/Calcium "Procter & Gamble"	400 mg + 500 mg calcium	Tablets	Oral use
EL - Greece	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 14KM OF NATIONAL HIGHWAY ATHENS-LAMIA KIFISSIA 14564	OSTOPOR	200MG/CAP	HARD CAPSULE	Oral use
EL - Greece	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 14KM OF NATIONAL HIGHWAY ATHENS-LAMIA KIFISSIA 14565	OSTOPOR	300MG/CAP	HARD CAPSULE	Oral use
EL - Greece	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES 14KM OF NATIONAL HIGHWAY ATHENS-LAMIA KIFISSIA 14566	OSTOPOR	400MG/CAP	HARD CAPSULE	Oral use
EL - Greece	PHARMACEUTICAL INDUSTRY PROEL EPAMEINONDAS G. KORONIS S.A.	ANFOZAN	400MG/CAP	HARD CAPSULE	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	LABORATORIOS VIÑAS, S.A. Provenza, 386 08025 Barcelona	OSTEUM	200 mg	tablets	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	DIDRONEL 200 mg, comprimé	200 mg	tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	DIDRONEL 400 mg, comprimé	400 mg	tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	DIPOROS 400 mg, comprimé	400 mg	tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ETIDRONATE DISODIQUE PROCTER & GAMBLE PHARMACEUTICALS 200 mg, comprimé	200 mg	tablet	Oral use
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	ETIDRONATE MYLAN 200 mg, comprimé	200 mg	tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	ETIDRONATE MYLAN 400 mg, comprimé	400 mg	tablet	Oral use
FR - France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	ETIDRONATE SANDOZ 400 mg, comprimé	400 mg	tablet	Oral use
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	ETIDRON	300 mg	Capsule	Oral use
NL - Netherlands	Procter & Gamble Pharmaceuticals Nederland B.V. Postbus 2507 3000 CM Rotterdam Netherlands	Didronel 400	400 mg	Tablet	Oral use
NL - Netherlands	Warner Chilcott Nederland B.V. Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Didrokit, combinatieverpakking	400 mg + 1250 mg	Tablet + Effervescent tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NO - Norway	Warner Chilcott UK Ltd.; Old Belfast Rd, Larne BT40 2SH, UK	Didronate + Calsium Kombinasjonspakning	400 mg/500 mg	tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Didronate	200 mg	tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Didronate 400 mg + Calcium 500 mg	Didronate 400 mg + Calcium 500 mg	tablet	Oral use
UK - United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL	ETIDRONATE DISODIUM	200mg	Tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	DIDRONEL	200mg	Tablets	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	DIDRONEL PMO	400mg	Tablets	Oral use
UK - United Kingdom	Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE19 8ET, UK	TILOETCA COMBI	400mg	Tablets	Oral use
UK - United Kingdom	Arrow Generics Limited, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom	DISODIUM ETIDRONATE	200mg	Tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Arrow Generics Limited, Unit 2 Eastman Way, Stevenage, Hertfordshire SG1 4SZ, United Kingdom	DISODIUM ETIDRONATE	400mg	Tablets	Oral use

Neridronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	NERIXIA	25 mg	Solution for injection	Intramuscular, Intravenous
IT - Italy	ABIOGEN PHARMA SpA Via Meucci, 36 - 56014 Ospedaletto (PI)	NERIXIA	100 mg	Concentrate for solution for infusion	Intravenous

Pamidronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Novartis Pharma GmbH, Stella-Klein-Löw-Weg 17, A-1020 Wien, Austria	Aredia 15 mg - Trockensubstanz zur Infusionsbereitung mit Lösungsmittel	15 mg/5 ml (Pamidronate Disodium)	Powder and solvent for solution for infusion	Intravenous
AT - Austria	Novartis Pharma GmbH, Stella-Klein-Löw-Weg 17, A-1020 Wien, Austria	Aredia 30 mg - Trockensubstanz zur Infusionsbereitung mit Lösungsmittel	30 mg/10 ml (Pamidronate Disodium)	Powder and solvent for solution for infusion	Intravenous
AT - Austria	Novartis Pharma GmbH, Stella-Klein-Löw-Weg 17, A-1020 Wien, Austria	Aredia 90 mg - Trockensubstanz zur Infusionsbereitung mit Lösungsmittel	90 mg/10 ml (Pamidronate Disodium)	Powder and solvent for solution for infusion	Intravenous
AT - Austria	Medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstraße 3 D-20354 Hamburg, Germany	Ebedronat 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous
AT - Austria	Hospira Deutschland GmbH Rablstraße 24 81669 München, Germany	Pamidronat Dinatrium Hospira 3 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	3 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous
AT - Austria	Hospira Deutschland GmbH Rablstraße 24 81669 München, Germany	Pamidronat Dinatrium Hospira 6 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	6 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous
AT - Austria	Hospira Deutschland GmbH Rablstraße 24 81669 München, Germany	Pamidronat Dinatrium Hospira 9 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	9 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Stada Arzneimittel GmbH, Muthgasse 36, A-1190 Wien, Austria	Pamidronat STADA 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous
AT - Austria	Torrex Chiesi Pharma GmbH Gonzagagasse 16/16, A- 1010 Wien, Austria	Pamitor 15 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	15 mg/ml (Pamidronate Disodium)	concentrate for solution for infusion	Intravenous
BE - Belgium	Novartis Pharma N.V. Medialaan 40 1800 Vilvoorde Belgium	Aredia	15 mg/5 ml	Powder for Solution for infusion	Intravenous
BE - Belgium	Novartis Pharma N.V. Medialaan 40 1800 Vilvoorde Belgium	Aredia	90 mg/10 ml	Powder for Solution for infusion	Intravenous
BE - Belgium	Teva Pharma Belgium N.V. Laarstraat 16 2610 Wilrijk Belgium	Pamidrin	3 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Actavis Group PTC EHF Reykjavíkuregur 76-78 220 Hafnarfjörður Iceland	Pamidronaat Actavis	3 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Actavis Group PTC EHF Reykjavíkuregur 76-78 220 Hafnarfjörður Iceland	Pamidronaat Actavis	6 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Actavis Group PTC EHF Reykjavíkuregur 76-78 220 Hafnarfjörður Iceland	Pamidronaat Actavis	9 mg/ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Hospira Benelux BVBA Stallestraat 63 1180 Brussels Belgium	Pamidronaatdinatrium Hospira	3 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Hospira Benelux BVBA Stallestraat 63 1180 Brussels Belgium	Pamidronaatdinatrium Hospira	6 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Hospira Benelux BVBA Stallestraat 63 1180 Brussels Belgium	Pamidronaatdinatrium Hospira	9 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Eurogenerics N.V. Heizel Esplanade b22 1020 Brussels Belgium	Pamidronate EG	3 mg/ml	Concentrate for solution for infusion	Intravenous
BE - Belgium	Mylan BVBA/SPRL Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Pamidronate Mylan	15 mg/ml	Concentrate for solution for infusion	Intravenous
BG - Bulgaria	Tchaikapharma High Quality Medicines, 1, G.M. Dimitrov Blvd, 1172 Sofia, Bulgaria	Pamitor	15mg/ml	Concentrate for solution for infusion	Intravenous
BG - Bulgaria	Novartis Pharma GmbH, Roonstrasse 25, D-90429 Nuernberg, Germany	Aredia	30 mg	powder and solvent for solution for infusion	Intravenous
BG - Bulgaria	Actavis Group PTC ehf, Iceland Reykjavikurvegur 76-78, IS-220, Hafnarfjordur	Clastodron	3 mg/ml,	concentrate for solution for infusion, 5 ml	Intravenous
BG - Bulgaria	Actavis Group PTC ehf, Iceland Reykjavikurvegur 76-78, IS-220, Hafnarfjordur	Clastodron	6 mg/ml	concentrate for solution for infusion - 10 ml	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BG - Bulgaria	Actavis Group PTC ehf, Iceland Reykjavikurvegur 76-78, IS-220, Hafnarfjordur	Clastodron	9 mg/ml	concentrate for solution for infusion - 10 ml	Intravenous
CY - Cyprus	PHARMACEUTICAL TRADING CO LTD, 18 THOUKIDIDOU STR, P O BOX 40628, 6306 LARNACA, CYPRUS	PAMIDRONATE DISODIUM CONCENTRATE FOR SOLUTION FOR INFUSION 9mg/ml	9mg/ml, 10ml	SOLUTION FOR INFUSION	Intravenous
CZ - Czech Republic	Novartis s.r.o., U nákladového nádraží 3265/10, 130 00 Praha- Strašnice (Nagano III.), Czech Republic	Aredia 15mg	1,5mg/ml	Powder and solvent for solution for infusion	Infusion
CZ - Czech Republic	Novartis s.r.o., U nákladového nádraží 3265/10, 130 00 Praha- Strašnice (Nagano III.), Czech Republic	Aredia 30mg	3mg/ml	Powder and solvent for solution for infusion	Infusion
CZ - Czech Republic	Medac Gesellschaft für klinische Spezialpräparate mbH, Fehlandtstraße 3, D- 20354 Hamburg, Germany	Pamidronate Medac 3mg/ml	3mg/ml	Concentrate for solution for infusion	Infusion
CZ - Czech Republic	Teva Pharmaceuticals CR, s.r.o., Radlická 3185/1c 150 00 Praha 5 Czech Republic	Pamidronate-Teva 3mg/ml	3mg/ml	Concentrate for solution for infusion	Infusion
CZ - Czech Republic	Torrex Chiesi CZ, s.r.o. , Na květnici 878/33, 140 00 Praha-Nusle, Czech Republic	Pamitor 15mg/ml	15mg/ml	Concentrate for solution for infusion	Infusion

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	axios Pharma GmbH Hauptstr. 198 D-33647 Bielefeld	axidronat 3mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	Cancernova GmbH onkologische Arzneimittel Lil-Dagover-Ring 7 D-82031 Grünwald	NOVAPAM 15 mg Pulver zur Herstellung einer Infusionslösung	15 mg	Powder for solution for infusion	Intravenous
DE - Germany	Cancernova GmbH onkologische Arzneimittel Lil-Dagover-Ring 7 D-82031 Grünwald	NOVAPAM 30 mg Pulver zur Herstellung einer Infusionslösung	30 mg	Powder for solution for infusion	Intravenous
DE - Germany	Cancernova GmbH onkologische Arzneimittel Lil-Dagover-Ring 7 D-82031 Grünwald	NOVAPAM 60 mg Pulver zur Herstellung einer Infusionslösung	60 mg	Powder for solution for infusion	Intravenous
DE - Germany	Cancernova GmbH onkologische Arzneimittel Lil-Dagover-Ring 7 D-82031 Grünwald	NOVAPAM 60 mg Pulver zur Herstellung einer Infusionslösung	60 mg	Powder for solution for infusion	Intravenous
DE - Germany	cell Pharm GmbH Theodor-Heuss-Str. 52 D-61118 Bad Vilbel	PAMIDRO-cell 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	TEVA Deutschland GmbH Wasastr. 50 D-01445 Radebeul	Pamidronat-GRY 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen	Pamidron HEXAL 15 mg/ml Konzentrat zur Herstellung einer Infusionslösung	15 mg	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	HIKMA Farmaceutica (Portugal) S.A. Estrada do Rio da Mo, 8,8 A e 8 B - Fervenca P-2705-906 TERRUGem SNT	Ribodronat 3 mg/ ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	Hospira Deutschland GmbH Rablstr. 24 D-81669 München	Pamidronat Hospira 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	Hospira Deutschland GmbH Rablstr. 24 D-81669 München	Pamidronat Hospira 6 mg/ml Konzentrat zur Herstellung einer Infusionslösung	6 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	Hospira Deutschland GmbH Rablstr. 24 D-81669 München	Pamidronat Hospira 9 mg/ml Konzentrat zur Herstellung einer Infusionslösung	9 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstr. 3 D-20354 Hamburg	Pamifos 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DE - Germany	Novartis Pharma GmbH Roonstr. 25 D-90429 Nürnberg	Aredia 15 mg	15 mg	Dry substance and solvent	Intravenous
DE - Germany	Novartis Pharma GmbH Roonstr. 25 D-90429 Nürnberg	Aredia 30 mg	30 mg	Dry substance and solvent	Intravenous
DE - Germany	Novartis Pharma GmbH Roonstr. 25 D-90429 Nürnberg	Aredia 90 mg	90 mg	Dry substance and solvent	Intravenous
DE - Germany	Novartis Pharma GmbH Roonstr. 25 D-90429 Nürnberg	Aredia 60 mg	60 mg	Dry substance and solvent	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Onkovis GmbH Grube 45 D-82377 Penzberg	Pamidronat Onkovis 3mg/ml Konzentrat zur Herstellung einer Infusionslösung	3 mg	Concentrate for solution for infusion	Intravenous
DK - Denmark	Helm AG, Nordkanalstrasse 28D, DE-20097 Hamburg, Germany	Epsilonat	15 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE- 61118 Bad Vilbel, Germany	Pamidrocell	3 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Hexal AG, Industriestrasse 25, DE-83607 Holzkirchen, Germany	Pamidronat "Hexal"	15 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Meda AS, Solvang 8, DK- 3450 Allerød, Denmark	Pamidronat "Meda"	15 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	BMM Pharma AB, Blasieholmsgatan 2, SE- 11148 Stockholm, Sweden	Pamidronatdinatrium "BMM Pharma"	3 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	BMM Pharma AB, Blasieholmsgatan 2, SE- 11148 Stockholm, Sweden	Pamidronatdinatrium "BMM Pharma"	6 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	BMM Pharma AB, Blasieholmsgatan 2, SE- 11148 Stockholm, Sweden	Pamidronatdinatrium "BMM Pharma"	9 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Hospira UK Limited, Queensway, Royal Leamington Spa, GB-CV31 3RW Warwickshire, England	Pamidronatdinatrium "Hospira"	3 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Hospira UK Limited, Queensway, Royal Leamington Spa, GB-CV31 3RW Warwickshire, England	Pamidronatdinatrium "Hospira"	6 mg/ml	Concentrat for infusion, solution	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Hospira UK Limited, Queensway, Royal Leamington Spa, GB-CV31 3RW Warwickshire, England	Pamidronatdinatrium "Hospira"	9 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	Teva Denmark A/S, Parallelvej 10-12, DK-2800 Kongens Lyngby, Denmark	Pamidronatdinatrium "Teva"	3 mg/ml	Concentrat for infusion, solution	Intravenous
DK - Denmark	medac, Gesellschaft fur klinisch, Spezialpraeparate mbH, Fehlandstrasse 3, DE-20354 Hamburg, Germany	Pamifos	3 mg/ml	Concentrat for infusion, solution	Intravenous
EL - Greece	HOSPIRA UK LIMITED, U.K. Queensway, Royal Leamington Spa Warwickshire CV31 3RW United Kingdom	PAMIDRONATE DISODIUM / HOSPIRA	6MG/1ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
EL - Greece	MEDICUS S.A. VALAORITOU 10 METAMORFOSI ATTIKIS 14452	PAMIDRONE	60MG/VIAL	POWDER AND SOLUTION FOR INFUSION	Intravenous
EL - Greece	MEDICUS S.A. VALAORITOU 10 METAMORFOSI ATTIKIS 14453	PAMIDRONE	90MG/VIAL	POWDER AND SOLUTION FOR INFUSION	Intravenous
EL - Greece	HOSPIRA UK LIMITED, U.K. Queensway, Royal Leamington Spa Warwickshire CV31 3RW United Kingdom	PAMIDRONATE DISODIUM / HOSPIRA	3MG/1 ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	HOSPIRA UK LIMITED, U.K. Queensway, Royal Leamington Spa Warwickshire CV31 3RW United Kingdom	PAMIDRONATE DISODIUM / HOSPIRA	6MG/1ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
EL - Greece	HOSPIRA UK LIMITED, U.K. Queensway, Royal Leamington Spa Warwickshire CV31 3RW United Kingdom	PAMIDRONATE DISODIUM / HOSPIRA	9MG/1ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
EL - Greece	ALAPIS ABEE AUTOKRATOROS NIKOLAOU 2 ATHENS 17671	PAMERIT	15MG/1ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
ES - Spain	HOSPIRA UK LIMITED Queensway. Royal Leamington Spa Warwickshire CV31 3RW Reino Unido	PAMIDRONATO HOSPIRA 3 mg/ml concentrado para solución para perfusión	3 mg/ml	Concentrate for solution for infusion	Intravenous
ES - Spain	HOSPIRA UK LIMITED Queensway. Royal Leamington Spa Warwickshire CV31 3RW Reino Unido	PAMIDRONATO HOSPIRA 6 mg/ml concentrado para solución para perfusión	6 mg/ml	Concentrate for solution for infusion	Intravenous
ES - Spain	HOSPIRA UK LIMITED Queensway. Royal Leamington Spa Warwickshire CV31 3RW Reino Unido	PAMIDRONATO HOSPIRA 9 mg/ml concentrado para solución para perfusión	9 mg/ml	Concentrate for solution for infusion	Intravenous
ES - Spain	NOVARTIS FARMACEUTICA, S.A.Gran Via de les Corts Catalanes, 764 08013 Barcelona	AREDIA 15 mg polvo y disolvente para solución para perfusión	15 mg polvo	solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	NOVARTIS FARMACEUTICA, S.A.Gran Via de les Corts Catalanes, 764 08013 Barcelona	AREDIA 30 mg polvo y disolvente para solución para perfusión	30 mg	solution for infusion	Intravenous
ES - Spain	NOVARTIS FARMACEUTICA, S.A.Gran Via de les Corts Catalanes, 764 08013 Barcelona	AREDIA 90 mg polvo y disolvente para solución para perfusión	90 mg	solution for infusion	Intravenous
ES - Spain	GENERIS FARMACÉUTICA, S.A.MOIÀ, 1, 2º 08006 BARCELONA	PAMIDRONATO GENERIS 15 mg/ml concentrado para solución para perfusión	15mg/ml	Concentrate for solution for infusion	Intravenous
ES - Spain	LABORATORIO STADA, S.L. Frederic Mompou, 5 08960 Sant Just Desvern	PAMIDRONATO STADA 3 mg/ml concentrado para solución para perfusión	3mg /ml	Concentrate for solution for infusion	Intravenous
ES - Spain	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH Fehlandtstrasse 3 Hamburg D-20354	PAMIFOS 3mg/ml concentrado para solución para perfusión	3mg /ml	Concentrate for solution for infusion	Intravenous
ES - Spain	LABORATORIO STADA, S.L. Frederic Mompou, 5 08960 Sant Just Desvern	PAMIDRONATO TEVA 3 mg/ml, concentrado para solución para perfusión	3mg /ml	Concentrate for solution for infusion	Intravenous
ES - Spain	COMBINO PHARM, S.L.Fructuos Gelabert, 6-8 08970 Sant Joan Despi	PAMIDRONATO DISODICO COMBINO PHARM 15 mg polvo para solución para perfusión	15mg	solution for infusion	Intravenous
ES - Spain	COMBINO PHARM, S.L.Fructuos Gelabert, 6-8 08970 Sant Joan Despi	PAMIDRONATO DISODICO COMBINO PHARM 30 mg polvo para solución para	30mg	solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
		perfusión			
ES - Spain	COMBINO PHARM, S.L.Fructuos Gelabert, 6-8 08970 Sant Joan Despi	PAMIDRONATO DISODICO COMBINO PHARM 60 mg polvo para solución para perfusión	60 mg	solution for infusion	Intravenous
ES - Spain	COMBINO PHARM, S.L.Fructuos Gelabert, 6-8 08970 Sant Joan Despi	PAMIDRONATO DISODICO COMBINO PHARM 90 mg polvo para solución para perfusión	90 mg	solution for infusion	Intravenous
ET - Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN-02130 Espoo FINLAND	AREDIA	15mg	Powder and solvent for solution for infusion	Intravenous
ET - Estonia	Torrex Chiesi Pharma GmbH Gonzagagasse 16/16, 1010 Vienna AUSTRIA	PAMITOR 15 MG/ML	15mg 1 ml	Concentrate for solution for infusion	Intravenous
FI - Finland	medac Gesellschaft für klinische Spezialpräparate mbH, Fehlandtstrasse 3, 20354 Hamburg, Germany	Pamifos	3 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Stada Arzneimittel AG, Stadastrasse 2 - 18, 61118 BAD VILBEL, Germany	Paminject	3 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Meda Oy, Vaisalantie 4, 02130 Espoo, Finland	Pamidronat Meda	15 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Hospira UK Limited, Queensway, Royal Leamington Spa, WARWICKSHIRE CV313RW, United Kingdom	Pamidronatdinatrium Hospira	3 mg/ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FI - Finland	Hospira UK Limited, Queensway, Royal Leamington Spa, WARWICKSHIRE CV313RW, United Kingdom	Pamidronatdinatrium Hospira	6 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	Hospira UK Limited, Queensway, Royal Leamington Spa, WARWICKSHIRE CV313RW, United Kingdom	Pamidronatdinatrium Hospira	9 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	BMM Pharma AB, Blasieholmsgatan 2, 11148 Stockholm, Sweden	Pamidronate BMM Pharma	3 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	BMM Pharma AB, Blasieholmsgatan 2, 11148 Stockholm, Sweden	Pamidronate BMM Pharma	6 mg/ml	Concentrate for solution for infusion	Intravenous
FI - Finland	BMM Pharma AB, Blasieholmsgatan 2, 11148 Stockholm, Sweden	Pamidronate BMM Pharma	9 mg/ml	Concentrate for solution for infusion	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	AREDIA 15 mg/5 ml, poudre et solvant pour solution pour perfusion	15 mg/5 ml	powder and solvent	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	AREDIA 60 mg/10 ml, poudre et solvant pour solution pour perfusion	60 mg/10 ml	powder and solvent	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	AREDIA 90 mg/10 ml, poudre et solvant pour solution pour perfusion	90 mg/10 ml	powder and solvent	Intravenous
FR - France	NORDIC PHARMA 216, boulevard Saint Germain 75007 Paris FRANCE	OSTEPAM 15 mg/ml, solution à diluer pour perfusion	15 mg/ml	solution	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	AGUETTANT 1, rue Alexander Fleming 69007 Lyon FRANCE	PAMIDRONATE DE SODIUM AGUETTANT 15 mg/5 ml, poudre et solvant pour solution pour perfusion	15 mg/5 ml	powder and solvent	Intravenous
FR - France	AGUETTANT 1, rue Alexander Fleming 69007 Lyon FRANCE	PAMIDRONATE DE SODIUM AGUETTANT 60 mg/10 ml, poudre et solvant pour solution pour perfusion	60 mg/10 ml	powder and solvent	Intravenous
FR - France	AGUETTANT 1, rue Alexander Fleming 69007 Lyon FRANCE	PAMIDRONATE DE SODIUM AGUETTANT 90 mg/10 ml, poudre et solvant pour solution pour perfusion	90 mg/10 ml	powder and solvent	Intravenous
FR - France	HOSPIRA FRANCE 17-19, rue Jeanne Braconnier Immeuble Volta 92360 Meudon La Forêt FRANCE	PAMIDRONATE DE SODIUM HOSPIRA 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous
FR - France	HOSPIRA FRANCE 17-19, rue Jeanne Braconnier Immeuble Volta 92360 Meudon La Forêt FRANCE	PAMIDRONATE DE SODIUM HOSPIRA 6 mg/ml, solution à diluer pour perfusion	6 mg/ml,	solution	Intravenous
FR - France	HOSPIRA FRANCE 17-19, rue Jeanne Braconnier Immeuble Volta 92360 Meudon La Forêt FRANCE	PAMIDRONATE DE SODIUM HOSPIRA 9 mg/ml, solution à diluer pour perfusion	9 mg/ml	solution	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	PAMIDRONATE DE SODIUM MYLAN 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	PAMIDRONATE DE SODIUM NOVARTIS PHARMA 15 mg/5 ml, poudre et solvant pour solution pour perfusion	15 mg/5 ml	powder and solvent	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	PAMIDRONATE DE SODIUM NOVARTIS PHARMA 60 mg/10 ml, poudre et solvant pour solution pour perfusion	60 mg/10 ml	powder and solvent	Intravenous
FR - France	NOVARTIS PHARMA 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	PAMIDRONATE DE SODIUM NOVARTIS PHARMA 90 mg/10 ml, poudre et solvant pour solution pour perfusion	90 mg/10 ml	powder and solvent	Intravenous
FR - France	RATIOPHARM (ALLEMAGNE) Graf Arco Strasse 3 89079 Ulm ALLEMAGNE	PAMIDRONATE DE SODIUM RATIOPHARM 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous
FR - France	TEVA SANTE Le Palatin 1 1 cours du Triangle 92936 Paris la Défense Cedex FRANCE	PAMIDRONATE DE SODIUM TEVA 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	PHARMAKI GENERICS (ROYAUME-UNI) 5 Bourlet Close W1W 7BL London ROYAUME-UNI	PAMIDRONATE PHARMAKI GENERICS 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous
FR - France	PHARMAKI GENERICS (ROYAUME-UNI) 5 Bourlet Close W1W 7BL London ROYAUME-UNI	PAMIDRONATE PHARMAKI GENERICS 6 mg/ml, solution à diluer pour perfusion	6 mg/ml	solution	Intravenous
FR - France	PHARMAKI GENERICS (ROYAUME-UNI) 5 Bourlet Close W1W 7BL London ROYAUME-UNI	PAMIDRONATE PHARMAKI GENERICS 9 mg/ml, solution à diluer pour perfusion	9 mg/ml	solution	Intravenous
FR - France	EG LABO - LABORATOIRES EUROGENERICS "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex FRANCE	PAMINJECT 3 mg/ml, solution à diluer pour perfusion	3 mg/ml	solution	Intravenous
HU - Hungary	Novartis Hungária Kft. Pharma részlege Bartók Béla út 43-47. Bartók-Ház, V. em. 1114 Budapest Hungary	AREDIA 30 mg por és oldószer oldatos infúzióhoz	30.0 mg Disodium pamidronate, anhydrous [from Disodium pamidronate pentahydrate	powder and solvent for solution for infusion	Parenteral

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, UK	PAMIDRONATE HOSPIRA 3 mg/ml koncentrátum oldatos infúzióhoz, 5 ml	3 mg/ml Pamidronic acid (equal to pamidronate disodium)	concentrate for solution for infusion	Parenteral
HU - Hungary	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, UK	PAMIDRONATE HOSPIRA 3 mg/ml koncentrátum oldatos infúzióhoz, 10 ml	3 mg/ml Pamidronic acid (equal to pamidronate disodium)	concentrate for solution for infusion	Parenteral
HU - Hungary	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, UK	PAMIDRONATE HOSPIRA 6 mg/ml koncentrátum oldatos infúzióhoz	6 mg/ml Pamidronic acid (equal to pamidronate disodium)	concentrate for solution for infusion	Parenteral
HU - Hungary	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, UK	PAMIDRONATE HOSPIRA 9 mg/ml koncentrátum oldatos infúzióhoz	9 mg/ml Pamidronic acid (equal to pamidronate disodium)	concentrate for solution for infusion	Parenteral
HU - Hungary	Medac GmbH Fehlandstrasse 3. 20354 Hamburg Germany	PAMIFOS 3 mg/ml koncentrátum oldatos infúzióhoz	3 mg/ml Disodium pamidronate (equal to Pamidronic acid)	concentrate for solution for infusion	Parenteral
HU - Hungary	Torrex Chiesi Pharma GmbH Gonzagagasse 16/16. 1010 Vienna Austria	PAMITOR 15 mg/ml koncentrátum oldatos infúzióhoz	15 mg/ ml Disodium pamidronate (equal to 12,6 mg pamidronic acid)	concentrate for solution for infusion	Parenteral

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK	Aredia	30mg	Powder and solvent for concentrate for solution for infusion	Slow intravenous infusion
IE - Ireland	Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK	Aredia	90mg	Powder and solvent for concentrate for solution for infusion	Slow intravenous infusion
IS - Iceland	Hospira UK Limited, Queensway Royale Leamington Spa, Warwickshire CV31 3RW United Kingdom	Pamidronatdinatrium Hospira 3 mg/ml	3 mg/ml	Concentrate for solution for infusion	Intravenous
IS - Iceland	Hospira UK Limited, Queensway Royale Leamington Spa, Warwickshire CV31 3RW United Kingdom	Pamidronatdinatrium Hospira 6 mg/ml	6 mg/ml	Concentrate for solution for infusion	Intravenous
IS - Iceland	Hospira UK Limited, Queensway Royale Leamington Spa, Warwickshire CV31 3RW United Kingdom	Pamidronatdinatrium Hospira 9 mg/ml	9 mg/ml	Concentrate for solution for infusion	Intravenous
IT - Italy	BIOINDUSTRIA L.I.M. SpA Via de Ambrosiis, 2 15067 Novi Ligure (AL)	PAMIDRONATO BIOINDUSTRIA LIM	15 mg/5 ml	Powder and solvent for concentrate for solution for infusion	Intravenous
IT - Italy	BIOINDUSTRIA L.I.M. SpA Via de Ambrosiis, 2 15067 Novi Ligure (AL)	PAMIDRONATO BIOINDUSTRIA LIM	30 mg/10 ml	Powder and solvent for concentrate for solution for infusion	Intravenous
IT - Italy	BIOINDUSTRIA L.I.M. SpA Via de Ambrosiis, 2 15067 Novi Ligure (AL)	PAMIDRONATO BIOINDUSTRIA LIM	60 mg/10 ml	Powder and solvent for concentrate for solution for infusion	Intravenous
IT - Italy	BIOINDUSTRIA L.I.M. SpA Via de Ambrosiis, 2 15067 Novi Ligure (AL)	PAMIDRONATO BIOINDUSTRIA LIM	90 mg/10 ml	Powder and solvent for concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	HIKMA ITALIA SpA Viale Certosa, 10 27100 Pavia	PAMIDRONATO DISODICO HIKMA	15 mg/5 ml	Solution for infusion	Intravenous
IT - Italy	HIKMA ITALIA SpA Viale Certosa, 10 27100 Pavia	PAMIDRONATO DISODICO HIKMA	30 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	HIKMA ITALIA SpA Viale Certosa, 10 27100 Pavia	PAMIDRONATO DISODICO HIKMA	60 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	HIKMA ITALIA SpA Viale Certosa, 10 27100 Pavia	PAMIDRONATO DISODICO HIKMA	90 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	HOSPIRA ITALIA Srl Via Orazio, 20/22 80122 Napoli	PAMIDRONATO DISODICO HIKMA Attenzione: E' Hospira	15 mg	Solution for injection	Intravenous
IT - Italy	HOSPIRA ITALIA Srl Via Orazio, 20/22 80122 Napoli	PAMIDRONATO DISODICO HOSPIRA	3 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	HOSPIRA ITALIA Srl Via Orazio, 20/22 80122 Napoli	PAMIDRONATO DISODICO HOSPIRA	6 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	HOSPIRA ITALIA Srl Via Orazio, 20/22 80122 Napoli	PAMIDRONATO DISODICO HOSPIRA	9 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	NOVARTIS FARMA SpA Largo Umberto Boccioni, 2 21040 Origgio (VA)	AREDIA	15 mg/5 ml	Powder and solvent for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	NOVARTIS FARMA SpA Largo Umberto Boccioni, 2 21040 Origgio (VA)	AREDIA	30 mg/10 ml	Powder and solvent for solution for infusion	Intravenous
IT - Italy	NOVARTIS FARMA SpA Largo Umberto Boccioni, 2 21040 Origgio (VA)	AREDIA	60 mg/10 ml	Powder and solvent for solution for infusion	Intravenous
IT - Italy	NOVARTIS FARMA SpA Largo Umberto Boccioni, 2 21040 Origgio (VA)	AREDIA	90 mg/10 ml	Powder and solvent for solution for infusion	Intravenous
IT - Italy	PHARMATEX ITALIA Srl Via Appiani, 22 20121 Milano	TEXPAMI	15 mg/5 ml	Solution for infusion	Intravenous
IT - Italy	PHARMATEX ITALIA Srl Via Appiani, 22 20121 Milano	TEXPAMI	30 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	PHARMATEX ITALIA Srl Via Appiani, 22 20121 Milano	TEXPAMI	60 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	PHARMATEX ITALIA Srl Via Appiani, 22 20121 Milano	TEXPAMI	90 mg/10 ml	Solution for infusion	Intravenous
IT - Italy	RATIOPHARM GMBH Graf Arco-strasse, 3 Ulm D-89070	PAMIDRONATO RATIOPHARM	3 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	TEVA ITALIA Srl Via Messina, 38 - 20154 Milano	PAMIDRONATO TEVA	3 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	CRINOS SpA Via Pavia, 6 20136 Milano	AMIDROX	3 mg/ml	concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	Actavis Itlay S.p.A. Via Luigi Pasteur, 10 20014 Nerviano (MI) Italy	PAMIDRONATO ACTAVIS	3 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	Actavis Itlay S.p.A. Via Luigi Pasteur, 10 20014 Nerviano (MI) Italy	PAMIDRONATO ACTAVIS	6 mg/ml	concentrate for solution for infusion	Intravenous
IT - Italy	Actavis Itlay S.p.A. Via Luigi Pasteur, 10 20014 Nerviano (MI) Italy	PAMIDRONATO ACTAVIS	9 mg/ml	concentrate for solution for infusion	Intravenous
LT - Lithuania	Torrex Chiesi -Pharma GmbH, Gonzagagasse 16/16, 1010 Viena, Austria	Pamitor	60 mg/4 ml	Concentrate for solution for infusion	Intravenous
LT - Lithuania	Torrex Chiesi -Pharma GmbH, Gonzagagasse 16/16, 1010 Viena, Austria	Pamitor	90 mg/6 ml	Concentrate for solution for infusion	Intravenous
LT - Lithuania	Torrex Chiesi -Pharma GmbH, Gonzagagasse 16/16, 1010 Viena, Austria	Pamitor	30 mg/2 ml	Concentrate for solution for infusion	Intravenous
LT - Lithuania	Torrex Chiesi -Pharma GmbH, Gonzagagasse 16/16, 1010 Viena, Austria	Pamitor	15 mg/ml	Concentrate for solution for infusion	Intravenous
LT - Lithuania	Hospira UK Limited, Queensway Royal Leamington Spa Warwickshire CV 31 3RW, United Kingdom	Pamidronate disodium Hospira	9 mg/ ml	Concentrate for solution for infusion	Intravenous
LT - Lithuania	Hospira UK Limited, Queensway Royal Leamington Spa Warwickshire CV 31 3RW, United Kingdom	Pamidronate disodium Hospira	6 mg/ ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LT - Lithuania	Hospira UK Limited, Queensway Royal Leamington Spa Warwickshire CV 31 3RW, United Kingdom	Pamidronate disodium Hospira	3 mg/ml	Concentrate for solution for infusion	Intravenous
LU - Luxembourg	NOVARTIS PHARMA GMBH 25, ROONSTRASSE D 90429 NUERNBERG	Aredia	15mg	powder for infusion	Intravenous
LU - Luxembourg	EUROGENERICS S.A ESPLANADE HEYSEL, B.22 B 1020 BRUXELLES	Paminject	3mg/ml	solution for infusion	Intravenous
LU - Luxembourg	HOSPIRA BENELUX SPRL 63, RUE DE STALLE B 1180 BRUXELLES	Pamidronate Disodique Hospira	3mg/ml	solution for infusion	Intravenous
LU - Luxembourg	HOSPIRA BENELUX SPRL 63, RUE DE STALLE B 1180 BRUXELLES	Pamidronate Disodique Hospira	6mg/ml	solution for infusion	Intravenous
LU - Luxembourg	TEVA PHARMA BELGIUM S.A. 16, LAARSTRAAT B 2610 WILRIJK	Pamidrin	3mg/ml	solution for infusion	Intravenous
LV - Latvia	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, 1010 Vienna, Austria	PAMITOR	15 mg/ml	Concentrate for solution for infusion	Intravenous
LV - Latvia	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, 1010 Vienna, Austria	PAMITOR	30 mg/2 ml	Concentrate for solution for infusion	Intravenous
LV - Latvia	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, 1010 Vienna, Austria	PAMITOR	60 mg/4ml	Concentrate for solution for infusion	Intravenous
LV - Latvia	Torrex Chiesi Pharma GmbH, Gonzagagasse 16/16, 1010 Vienna,	PAMITOR	90 mg/6 ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	Austria				
MT - Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR England	Aredia	15mg	powder and solvent for solution for infusion	Intravenous
MT - Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR England	Aredia	30mg	powder and solvent for solution for infusion	Intravenous
MT - Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR England	Aredia	60mg	powder and solvent for solution for infusion	Intravenous
MT - Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR England	Aredia	90mg	powder and solvent for solution for infusion	Intravenous
NL - Netherlands	Nordic Pharma B.V. Tolweg 15 3741 LM Baarn Netherlands	Pamidronaat dinatrium 15 mg	15 mg	Powder for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Nordic Pharma B.V. Tolweg 15 3741 LM Baarn Netherlands	Pamidronaat dinatrium 30 mg	30 mg	Powder for solution for infusion	Intravenous
NL - Netherlands	Nordic Pharma B.V. Tolweg 15 3741 LM Baarn Netherlands	Pamidronaat dinatrium 60 mg	60 mg	Powder for solution for infusion	Intravenous
NL - Netherlands	Nordic Pharma B.V. Tolweg 15 3741 LM Baarn Netherlands	Pamidronaat dinatrium 90 mg	90 mg	Powder for solution for infusion	Intravenous
NL - Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem Netherlands	Pamidronaatdinatrium 3 mg/ml PCH	3 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	All-gen Pharmaceuticals & Generics B.V. Rouboslaan 32 2252 TR Voorschoten Netherlands	Pamidronaatdinatrium Allgen 3 mg/ml	3 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	All-gen Pharmaceuticals & Generics B.V. Rouboslaan 32 2252 TR Voorschoten Netherlands	Pamidronaatdinatrium Allgen 6 mg/ml	6 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	All-gen Pharmaceuticals & Generics B.V. Rouboslaan 32 2252 TR Voorschoten Netherlands	Pamidronaatdinatrium Allgen 9 mg/ml	9 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	Hospira Benelux BVBA, Stallestraat 63 1180 Brussel Belgium	Pamidronaatdinatrium Hospira 3 mg/ml	3 mg/ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Hospira Benelux BVBA, Stallestraat 63 1180 Brussel Belgium	Pamidronaatdinatrium Hospira 6 mg/ml	6 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	Hospira Benelux BVBA, Stallestraat 63 1180 Brussel Belgium	Pamidronaatdinatrium Hospira 9 mg/ml	9 mg/ml	Concentrate for solution for infusion	Intravenous
NL - Netherlands	Medac Gesellschaft für klinische Spezialpräparate mbH Fehlandtstr. 3 20354 Hamburg Germany	Pamipro 3 mg/ml	3 mg/ml	Concentrate for solution for infusion	Intravenous
NO - Norway	Meda, postboks 194, 1371 Asker Norawy	Pamidronat Meda	15 mg/ml	Concentrate for solution for infusion	Intravenous
NO - Norway	Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW Warwickshire, Great Britain	Pamidronatdinatrium Hospira	3 mg/ml	Concentrate for solution for infusion	Intravenous
NO - Norway	Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW Warwickshire, Great Britain	Pamidronatdinatrium Hospira	6 mg/ml	Concentrate for solution for infusion	Intravenous
NO - Norway	Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW Warwickshire, Great Britain	Pamidronatdinatrium Hospira	9 mg/ml	Concentrate for solution for infusion	Intravenous
PL - Poland	Hospira UK Limited Queensway, CV31 3RW, Royal Leamington Spa, Warwickshire, United Kingdom	Pamisol 3 mg/ml	3 mg/ml	concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Hospira UK Limited Queensway, CV31 3RW, Royal Leamington Spa, Warwickshire, United Kingdom	Pamisol 6 mg/ml	6 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	Farmacom Sp. z o.o. Mogilska 80 st. 31-546, Cracow, Poland	Pamidia	3 mg	concentrate for solution for infusion	Intravenous
PL - Poland	Farmacom Sp. z o.o. Mogilska 80 st. 31-546, Cracow, Poland	Pamidia	6 mg	concentrate for solution for infusion	Intravenous
PL - Poland	Farmacom Sp. z o.o. Mogilska 80 st. 31-546, Cracow, Poland	Pamidia	9 mg	concentrate for solution for infusion	Intravenous
PL - Poland	medac Gesellschaft fur klinische Specialpreparate mbH Theaterstrasse 6 22880 Wedel / Germany	Pamidronat medac 3 mg / ml	3 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	ratiopharm GmbH Graf-Arco-Strasse 3, Ulm, 89073, Germany	Pamidronat- ratiopharm	3 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	VIPHARM S.A. Przewoźników st.11 03-691 Warsaw, Poland	Pamifos-15	15 mg	powder and solvent for solution for infusion	Intravenous
PL - Poland	VIPHARM S.A. Przewoźników st.11 03-691 Warsaw, Poland	Pamifos-30	30 mg	powder and solvent for solution for infusion	Intravenous
PL - Poland	VIPHARM S.A. Przewoźników st.11 03-691 Warsaw, Poland	Pamifos-60	60 mg	powder and solvent for solution for infusion	Intravenous
PL - Poland	VIPHARM S.A. Przewoźników st.11 03-691 Warsaw, Poland	Pamifos-90	90 mg	powder and solvent for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	STADA Arzneimittel AG Stadastraße 2-18 61118 Bad Vilbel, Germany	Pamistad	3 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	Torrex Chiesi Pharma GmbH Gonzagagasse 16/16, A-1010 Vienna, Austria	Pamitor	15 mg/ml	concentrate for solution for infusion	Intravenous
PL - Poland	Novartis Pharma GmbH Roonstraße 25 D-90429 Nürnberg, Germany	Aredia	60 mg	powder and solvent for solution for infusion	Intravenous
PL - Poland	Novartis Pharma GmbH Roonstraße 25 D-90429 Nürnberg, Germany	Aredia	90 mg	powder and solvent for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	3 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	6 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	9 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Pamidronato APS	15 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436	Pamidronato Azevedos 15 mg Pó para perfusão	15 mg	Powder for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	Alcabideche Portugal				
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 30 mg Pó para perfusão	30 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 90 mg Pó para perfusão	90 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 60 mg Pó para perfusão	60 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Teva Pharma - Produtos Farmacêuticos, Lda. Edifício Cyprium, Av. 25 de Abril, 15, 2º F, 2795-195 Linda-a-Velha Portugal	Pamidronato Teva	3 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	3 mg/ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	6 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	9 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	3 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	6 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hospira Portugal, Lda. Rua Amália Rodrigues, n.º 240, 2750-228 Cascais Portugal	Pamidran	9 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Pamidronato APS	15 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 15 mg Pó para perfusão	15 mg	Powder for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 30 mg Pó para perfusão	30 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 90 mg Pó para perfusão	90 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Pamidronato Azevedos 60 mg Pó para perfusão	60 mg	Powder for solution for infusion	Intravenous
PT - Portugal	Teva Pharma - Produtos Farmacêuticos, Lda. Edifício Cyprium, Av. 25 de Abril, 15, 2º F, 2795-195 Linda-a-Velha Portugal	Pamidronato Teva	3 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	3 mg/ml	Concentrate for solution for infusion	Intravenous
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	6 mg/ml	Concentrate for solution for infusion	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Hikma Farmacêutica (Portugal), S.A. Estrada do Rio da Mó, 8 - 8 A/B - Fervença, 2705-906 Terrugem (SNT) Portugal	Pamidronato Hikma	9 mg/ml	Concentrate for solution for infusion	Intravenous
RO - Romania	NOVARTIS PHARMA GmbH Roonstrasse 25 D-90429 Nürnberg, Germany	AREDIA 15 mg/ml powder and solvent for solution for infusion	15 mg/ml	powder and solvent for solution for infusion	Parenteral
RO - Romania	TORREX CHIESI PHARMA GmbH Gonzagagasse 16/16, A-1010, Viena, Austria	PAMIDRONAT TORREX 15 mg/ml powder for solution for infusion	15 mg/ml	powder for solution for infusion	Parenteral
RO - Romania	DR. REDDY'S LABORATORIES Str. Av. Petre Crețu, nr.74, Sector 1, București, Romania	PAMIRED 60 powder for solution for infusion	60 mg	powder for solution for infusion	Parenteral
RO - Romania	DR. REDDY'S LABORATORIES Str. Av. Petre Crețu, nr.74, Sector 1, București, Romania	PAMIRED 30 powder for solution for infusion	30 mg	powder for solution for infusion	Parenteral
SE - Sweden	Hospira UK Limited Queensway Royal Leamington Spa Warwickshire, CV31 3RW United Kingdom	Pamidronatdinatrium Hospira	3 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	Hospira UK Limited Queensway Royal Leamington Spa Warwickshire, CV31 3RW United Kingdom	Pamidronatdinatrium Hospira	6 mg/ml	concentrate for solution for infusion	For infusion

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Hospira UK Limited Queensway Royal Leamington Spa Warwickshire, CV31 3RW United Kingdom	Pamidronatdinatrium Hospira	9 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	Meda AB 170 09 Solna Sweden	Pamidronat Meda	15 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	Teva Sweden AB Box 1070 251 10 Helsingborg Sweden	Pamidronat Teva	3 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	STADA Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Germany	Pamidrocell	3 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	BMM Pharma AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Pamidronate BMM Pharma	3 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	BMM Pharma AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Pamidronate BMM Pharma	6 mg/ml	concentrate for solution for infusion	For infusion
SE - Sweden	BMM Pharma AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Pamidronate BMM Pharma	9 mg/ml	concentrate for solution for infusion	For infusion
SI - Slovenia	Novartis Pharma GmbH, Roonstrasse 25, Nuernberg D-90429 , Germany	Aredia 15 mg prašek in vehikel za koncentrat za raztopino za infundiranje	15 mg	powder and solvent for solution for injection	Intravenous
SI - Slovenia	Novartis Pharma GmbH, Roonstrasse 25, Nuernberg D-90429 , Germany	Aredia 30 mg prašek in vehikel za koncentrat za raztopino za	30 mg	powder and solvent for solution for injection	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
		infundiranje			
SI - Slovenia	Torrex Chiesi Slovenija d.o.o., Trdinova 4, SI-1000 Ljubljana, Slovenia	Pamitor 30 mg koncentrat za raztopino za infundiranje	12,6 mg/ ml	powder and solvent for solution for injection	Intravenous
SI - Slovenia	Torrex Chiesi Slovenija d.o.o., Trdinova 4, SI-1000 Ljubljana, Slovenia	Pamitor 60 mg koncentrat za raztopino za infundiranje	12,6 mg/ ml	powder and solvent for solution for injection	Intravenous
SI - Slovenia	Torrex Chiesi Slovenija d.o.o., Trdinova 4, SI-1000 Ljubljana, Slovenia	Pamitor 90 mg koncentrat za raztopino za infundiranje	12,6 mg/ ml	powder and solvent for solution for injection	Intravenous
SK - Slovakia	Torrex Chiesi -Pharma GmbH, Gonzagagasse 16/16, 1010 Viena, Austria	Pamitor 15 mg/ml	15 mg/ml	concentrate for solution for infusion	Intravenous
SK - Slovakia	medac GmbH Theaterstraße 6 D-22880 Wedel Germany	PAMIFOS	3 mg/ml	Concentrate for infusion	Intravenous
UK - United Kingdom	Novartis Pharmaceuticals UK Limited, Frimly Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK	AREDIA DRY POWDER	15 mg	Powder for Injection	Intravenous
UK - United Kingdom	Novartis Pharmaceuticals UK Limited, Frimly Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK	AREDIA DRY POWDER	30 mg	Powder for Injection	Intravenous
UK - United Kingdom	Novartis Pharmaceuticals UK Limited, Frimly Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK	AREDIA DRY POWDER	90 mg	Powder for Injection	Intravenous

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Actavis Group PTC EHF, Reykjavikurvegi 76-78, Hafnarfirdi IS-220 Iceland	PAMIDRONATE DISODIUM	3MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
UK - United Kingdom	Actavis Group PTC EHF, Reykjavikurvegi 76-78, Hafnarfirdi IS-220 Iceland	PAMIDRONATE DISODIUM	6MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
UK - United Kingdom	Actavis Group PTC EHF, Reykjavikurvegi 76-78, Hafnarfirdi IS-220 Iceland	PAMIDRONATE DISODIUM	9MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
UK - United Kingdom	Apsala Limited, bayview House, 49 Northstrand Road,Dublin 3, Ireland	DISODIUM PAMIDRONATE	3MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
UK - United Kingdom	Apsala Limited, bayview House, 49 Northstrand Road,Dublin 3, Ireland	DISODIUM PAMIDRONATE	6MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous
UK - United Kingdom	Apsala Limited, bayview House, 49 Northstrand Road,Dublin 3, Ireland	DISODIUM PAMIDRONATE	9MG/ML	CONCENTRATE FOR SOLUTION FOR INFUSION	Intravenous

Risedronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	sanofi-aventis GmbH ÖSTERREICH SATURN Tower, Leonard- Bernstein-Straße 10 A-1220 Wien, Austria	Actonel Combi Filmdabletten	35 mg (risedronate sodium) + 500 mg/400 UI	film-coated tablets	Oral use
AT - Austria	sanofi-aventis GmbH SATURN Tower, Leonard- Bernstein-Straße 10 A-1220 Wien, Austria	Actonel einmal wöchentlich 35 mg Filmdabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	sanofi-aventis GmbH SATURN Tower, Leonard- Bernstein-Straße 10 A-1220 Wien, Austria	Actonel 30 mg Filmdabletten	30 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	sanofi-aventis GmbH SATURN Tower, Leonard- Bernstein-Straße 10 A-1220 Wien, Austria	Actonel 5 mg Filmdabletten	5 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	sanofi-aventis GmbH SATURN Tower, Leonard- Bernstein-Straße 10 A-1220 Wien, Austria	Actonel 75 mg Filmdabletten	75 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	Arcana Arzneimittel GmbH, Hütteldorfer Straße 299, A-1140 Wien, Austria	Risedronat Arcana einmal wöchentlich 35 mg - Filmdabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Hexal Pharma GmbH, Stella- Klein-Löw-Weg 17, A-1020 Wien, Austria	Risedronat Hexal einmal wöchentlich 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	1A Pharma GmbH, Stella- Klein-Löw-Weg 17, A-1020 Wien, Austria	Risedronat 1A Pharma einmal wöchentlich 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert-Schweitzer Gasse 3 A-1140 Wien Austria	Risedronat-ratiopharm einmal wöchentlich 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	Sandoz GmbH, Biochemiestraße 10 A-6250 Kundl, Austria	Risedronat Sandoz einmal wöchentlich 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	Stada Arzneimittel GmbH Muthgasse 36 A-1190 Wien Austria	Risedronat STADA einmal wöchentlich 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use
AT - Austria	TEVA Pharma B.V. Computerweg 10 3542 DR Utrecht Netherlands	Risedronat Teva 35 mg Filmtabletten	35 mg (risedronate sodium)	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	5 mg	Film-Coated Tablets	Oral Use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	30 mg	Film-Coated Tablets	Oral Use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	35 mg	Film-Coated Tablets	Oral Use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	75 mg	Film-Coated Tablets	Oral Use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel Combi	35 mg + 1250 mg calcium	Film-Coated Tablets	Oral Use
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel Combi D	35 mg + 1000 mg / 880 IU	Film-Coated Tablets and effervescent granules	Oral Use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel Plus calcium D	35 mg + 500 mg / 400 UI	Film-Coated Tablets	Oral use
BE - Belgium	TEVA Pharma Belgium N.V, Laarstraat 16, B-2610 Wilrijk, Belgium	Risedronate Teva 35 mg filmomhulde tabletten	35mg	film-coated tablets	Oral use
BG - Bulgaria	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	5 mg	Film-coated tablets	Oral use
BG - Bulgaria	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	35 mg	Film-coated tablets	Oral use
BG - Bulgaria	Sanofi-Aventis Bulgaria EODD 103, blvd Al. Stamboliyski Office Building Sofia Tower Level 8, 1303 Sofia Bulgaria	ACTONEL 5 MG FILM- COATED TABLETS	5 mg	Film-Coated Tablets	Oral use
BG - Bulgaria	Sanofi-Aventis Bulgaria EODD 103, blvd Al. Stamboliyski Office Building Sofia Tower Level 8, 1303 Sofia Bulgaria	ACTONEL 30 MG FILM- COATED TABLETS	30 mg	Film-Coated Tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BG - Bulgaria	Sanofi-Aventis Bulgaria EOOD 103, blvd Al. Stamboliyski Office Building Sofia Tower Level 8, 1303 Sofia Bulgaria	ACTONEL ONCE A WEEK 35 MG FILM- COATED TABLETS	35 mg	Film-Coated Tablets	Oral use
BG - Bulgaria	Sanofi-Aventis Bulgaria EOOD 103, blvd Al. Stamboliyski Office Building Sofia Tower Level 8, 1303 Sofia Bulgaria	ACTONEL 75 MG FILM- COATED TABLETS	75 mg	Film-Coated Tablets	Oral use
BG - Bulgaria	ZENTIVA, k.s. U kabelovny 130, Dolní Měcholupy 102 37 Praga 10, Czech Republic	RISENDROS 35 mg	35 mg	film-coated tablets	Oral use
BG - Bulgaria	ratiopharm GmbH, Graf- Arco-Strasse 3, 89079 Ulm, Germany	Risedronat-ratiopharm	35 mg	film - coated tablets	Oral use
BG - Bulgaria	Vale Pharmaceuticals Ltd 1B Gurtnafleur Business Park, Gurtnafleur, clonmel, Co. Tipperary IRELAND	RIGAT	35 mg	film - coated tablets	Oral use
BG - Bulgaria	Stada Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel,Germany	Zilar	5 mg	film - coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BG - Bulgaria	Teva Pharmaceuticals N.V.Gogol 15 ЕООД Sofia Bulgaria	Rizida	35 mg	film - coated tablets	Oral use
BG - Bulgaria	Genericon Pharma Gesellschaft m.b.H, Hafnerstabe 211, 8054 Graz, Austria	Risedronat Genericon	5 mg	film - coated tablets	Oral use
BG - Bulgaria	Genericon Pharma Gesellschaft m.b.H, Hafnerstabe 211, 8054 Graz, Austria	Risedronat Genericon	30 mg	film - coated tablets	Oral use
BG - Bulgaria	Genericon Pharma Gesellschaft m.b.H, Hafnerstabe 211, 8054 Graz, Austria	Risedronat Genericon	35 mg	film - coated tablets	Oral use
BG - Bulgaria	Actavis Group PTC ehf, Reykjavikurvegur 76-78, 220 Hafnarjardur, Iceland	Risadis	5 mg	film - coated tablets	Oral use
BG - Bulgaria	Actavis Group PTC ehf, Reykjavikurvegur 76-78, 220 Hafnarjardur, Iceland	Risadis	35 mg	film - coated tablets	Oral use
CY - Cyprus	SANOFI AVENTIS CYPRUS LTD, CHARALAMBOU MOUSKOU 14, 2015 STROVOLOS, CYPRUS	ACTONEL TABLET 5MG	5MG	TABLET	Oral use
CY - Cyprus	SANOFI AVENTIS CYPRUS LTD, CHARALAMBOU MOUSKOU 14, 2015	ACTONEL OAW/"ONCE A WEEK" TABLETS 35MG	35MG	TABLET	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	STROVOLOS, CYPRUS				
CY - Cyprus	SANOFI AVENTIS CYPRUS LTD, CHARALAMBOU MOUSKOU 14, 2015 STROVOLOS, CYPRUS	ACTONEL (2 CONSEQUENTIAL DAYS PER MONTH)	75MG	TABLET	Oral use
CY - Cyprus	ACTAVIS GROUP PTC ehf., REYKJAVIKURVEGUR 76-78, 220 HAFNAFJORDUR, ICELAND	BIFODRON TABLETS 5MG	5MG	TABLET	Oral use
CY - Cyprus	ACTAVIS GROUP PTC ehf., REYKJAVIKURVEGUR 76-78, 220 HAFNAFJORDUR, ICELAND	BIFODRON TABLETS 30MG	30MG	TABLET	Oral use
CY - Cyprus	ACTAVIS GROUP PTC ehf., REYKJAVIKURVEGUR 76-78, 220 HAFNAFJORDUR, ICELAND	BIFODRON TABLETS 35MG	35MG	TABLET	Oral use
CY - Cyprus	BEACON PHARMACEUTICAL LIMITED, 85 HIGH STREET, TUNBIDGE WELLS TN1 1YG, UK	RISEDRONATE SODIUM TABLET 5MG	5MG	TABLET	Oral use
CY - Cyprus	BEACON PHARMACEUTICAL LIMITED, 85 HIGH STREET, TUNBIDGE WELLS TN1 1YG, UK	RISEDRONATE SODIUM TABLET 30MG	30MG	TABLET	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CY - Cyprus	BEACON PHARMACEUTICAL LIMITED, 85 HIGH STREET, TUNBIDGE WELLS TN1 1YG, UK	RISEDRONATE SODIUM TABLET 35MG	35MG	TABLET	Oral use
CY - Cyprus	P T HADJIGEORGIOU CO LTD, 31 YILDIZ, P O BOX 53158, 3301 LEMESOS, CYPRUS	ATRONATE "ONCE A WEEK" TABLETS 35MG	35MG	TABLET	Oral use
CY - Cyprus	PHARMATHEN SA, DERVENAKION 6, 15351 PALLINI ATTIKI, GREECE	RISEPALLIN TABLETS 5MG	5MG	TABLET	Oral use
CY - Cyprus	PHARMATHEN SA, DERVENAKION 6, 15351 PALLINI ATTIKI, GREECE	RISEPALLIN TABLETS 30MG	30MG	TABLET	Oral use
CY - Cyprus	PHARMATHEN SA, DERVENAKION 6, 15351 PALLINI ATTIKI, GREECE	RISEPALLIN TABLETS 35MG	35MG	TABLET	Oral use
CY - Cyprus	Arrow Generics Limited, Unit 2 Eastman Way,Hertfordshire, SG1 4SZ,Stevenage,UK	RISEDRONATE ARROW TABLETS 35MG	35MG	TABLET	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Sanofi-Aventis s.r.o., Evropská 846/176a, 160 00 Praha-Dejvice, Czech Republic	Actonel 30mg	30mg	Film-coated tablet	Oral use
CZ - Czech Republic	Sanofi-Aventis s.r.o., Evropská 846/176a, 160 00 Praha-Dejvice, Czech Republic	Actonel 35mg	35mg	Film-coated tablet	Oral use
CZ - Czech Republic	Sanofi-Aventis s.r.o., Evropská 846/176a, 160 00 Praha-Dejvice, Czech Republic	Actonel 5mg	5mg	Film-coated tablet	Oral use
CZ - Czech Republic	S.C. LaborMed Pharma S.A., Bd. Theodor Pallady nr. 44B, sector 3, Bucharest, Romania	Juverital 35mg potahované tablety	35mg	Film-coated tablet	Oral use
CZ - Czech Republic	S.C. LaborMed Pharma S.A., Bd. Theodor Pallady nr. 44B, sector 3, Bucharest, Romania	Juverital 5mg potahované tablety	5mg	Film-coated tablet	Oral use
CZ - Czech Republic	Sanofi-Aventis s.r.o., Evropská 846/176a, 160 00 Praha-Dejvice, Czech Republic	Norsed 35mg	35mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Galex d.d., Tišinska ul. 29g, 9000 Murska Sobota, Slovenia	Risedronat Galex 35mg	35mg	Film-coated tablet	Oral use
CZ - Czech Republic	Galex d.d., Tišinska ul. 29g, 9000 Murska Sobota, Slovenia	Risedronat Galex 5mg	5mg	Film-coated tablet	Oral use
CZ - Czech Republic	Generics Ltd., Mylan Albany Gate, Darkes Lane, Potters Bar Hertfordshire EN6 1AG United Kingdom	Risedronat Mylan 35mg	5mg	Film-coated tablet	Oral use
CZ - Czech Republic	Teva Pharmaceuticals CR, s.r.o., Radlická 3185/1c 150 00 Praha 5 Czech Republic	Risedronat Teva 35mg	5mg	Film-coated tablet	Oral use
CZ - Czech Republic	Ratiopharm GmbH, Graf- Arco-Straße 3 89079 Ulm, Germany	Risedronat-Ratiopharm 35mg	35mg	Film-coated tablet	Oral use
CZ - Czech Republic	ZENTIVA, k.s. U kabelovny 130, Dolní Měcholupy 102 37 Praga 10, Czech Republic	Risendros 35mg	35mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
CZ - Czech Republic	Ingers Industrial Solutions, s.r.o. , Slunná 271/16, 617 00 Brno-Komárov, Czech Republic	Tevanel 35mg	35mg	Film-coated tablet	Oral use
CZ - Czech Republic	Zaklad Farmaceutyczny Adamed Pharma S.A., Szkolna Street 33, 95-054 Ksawerow, Poland	NORIFAZ 35MG POTAHOVANÉ TABLETY	35 mg	Film-coated tablet	Oral use
DE - Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Risedronat AL 35 mg Filmdabletten	35 mg	Film-coated tablet	Oral use
DE - Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel	Risedronat STADA 35 mg Filmdabletten	35 mg	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel 5 mg Filmdabletten	5 mg	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel 30 mg Filmdabletten	30 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel 75 mg Filmdabletten	75 mg	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel einmal wöchentlich 35 mg Filmdabletten	35 mg	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Norsed einmal wöchentlich 35 mg Filmdabletten	35 mg	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel 35 mg plus Calcium Filmdabletten	35 mg + 1250 mg calcium	Film-coated tablet	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel plus Calcium D 35 mg + 1000 mg/880 I.E. Filmdabletten + Brausegranulat	35 mg + 1000mg / 800 IU	Film-coated tablet and Effervescent granules	Oral use
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Norsed plus Calcium D 35 mg + 1000 mg/880 I.E. Filmdabletten + Brausegranulat	35 mg + 1000mg / 800 IU	Film-coated tablet and Effervescent granules	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Warner Chilcott Deutschland GmbH Dr.-Otto-Röhm-Str. 2 - 4 D-64331 Weiterstadt	Actonel plus Calcium D 35 mg + 500 mg/400 I.E. Filmtabletten	35 mg + 500mg / 400 IU	Film-coated tablet and	Oral use
DE - Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg	Risedronat Heumann 35 mg Filmtabletten	40,17 mg	Film-coated tablet	Oral use
DK - Denmark	Ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Risostad	5 mg	Film-coated tablets	Oral use
DK - Denmark	Ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Risostad	35 mg	Film-coated tablets	Oral use
DK - Denmark	Mylan AB, P.O.box 23033, Ynglingagatan 14, SE-104 35 Stockholm; Sweden	Vionate	5 mg	Film-coated tablets	Oral use
DK - Denmark	Mylan AB, P.O.box 23033, Ynglingagatan 14, SE-104 35 Stockholm; Sweden	Vionate	35 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Dimidronat	5 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Dimidronat	30 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Dimidronat	35 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Ellidronat	35 mg	Film-coated tablets	Oral use
DK - Denmark	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	5 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	35 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Karadronat	5 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Karadronat	30 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Karadronat	35 mg	Film-coated tablets	Oral use
DK - Denmark	Zakład Farmaceutyczny, Adamed Phama S.a, 33 Szkołna Street, PL-95054 Ksawerów; Poland	Norifaz	35 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Sanofi-Aventis Denmark A/S, Slotsmarken 13, DK- 3970 Hørsholm, Denmark	Optinate	5 mg	Film-coated tablets	Oral use
DK - Denmark	Sanofi-Aventis Denmark A/S, Slotsmarken 13, DK- 3970 Hørsholm, Denmark	Optinate	30 mg	Film-coated tablets	Oral use
DK - Denmark	Sanofi-Aventis Denmark A/S, Slotsmarken 13, DK- 3970 Hørsholm, Denmark	Optinate	75 mg	Film-coated tablets	Oral use
DK - Denmark	Sanofi-Aventis Denmark A/S, Slotsmarken 13, DK- 3970 Hørsholm, Denmark	Optinate Combi	35 mg + 1250 mg calcium	Film-coated tablets	Oral use
DK - Denmark	Sanofi-Aventis Denmark A/S, Slotsmarken 13, DK- 3970 Hørsholm, Denmark	Optinate Septimum	35 mg	Film-coated tablets	Oral use
DK - Denmark	CT Arzneimittel GmbH, Lengeder Str. 42A, DE- 13407 Berlin, Germany	Racidrix	35 mg	Film-coated tablets	Oral use
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Ridracid	35 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Ratiopharm GmbH, Graf-Arco-Strasse 3, DE-89079 Ulm, Germany	Rinon	35 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risdronostad	5 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risdronostad	30 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risdronostad	35 mg	Film-coated tablets	Oral use
DK - Denmark	Actavis Group PTC ehf., PO Box 425, Reykjavikurvegi 76-78, IS-220 Hafnarfjörður, Iceland	Risedronatnatrium "Actavis"	35 mg	Film-coated tablets	Oral use
DK - Denmark	Orifarm Generics A/S, Energivej 15, DK-5260 Odense S., Denmark	Risedronatnatrium "Orifarm"	5 mg	Film-coated tablets	Oral use
DK - Denmark	Orifarm Generics A/S, Energivej 15, DK-5260 Odense S., Denmark	Risedronatnatrium "Orifarm"	30 mg	Film-coated tablets	Oral use
DK - Denmark	Orifarm Generics A/S, Energivej 15, DK-5260 Odense S., Denmark	Risedronatnatrium "Orifarm"	35 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risedronatnatrium "Stada"	5 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risedronatnatrium "Stada"	30 mg	Film-coated tablets	Oral use
DK - Denmark	Stada Arzneimittel AG, Stadastrasse 2-8, DE-61118 Bad Vilbel, Germany	Risedronatnatrium "Stada"	35 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DK - Denmark	Teva Denmark A/S, Parallevej 10-12, DK-2800 Kongens Lyngby, Denmark	Risedronatnatrium "Teva"	35 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Risepallin	5 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Risepallin	30 mg	Film-coated tablets	Oral use
DK - Denmark	Pharmathen S.A., Dervenakion str. 6, GR- 15351 Pallini Attiki, Greece	Risepallin	35 mg	Film-coated tablets	Oral use
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Riseratio	35 mg	Film-coated tablets	Oral use
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Risonat	35 mg	Film-coated tablets	Oral use
EL - Greece	SANOFI-AVENTIS AEBE SYNGROU AVENUE 348 BUILDING A KALITHEA 17674	ACTONEL	5MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	SANOFI-AVENTIS AEBE SYNGROU AVENUE 348 BUILDING A KALITHEA 17675	ACTONEL	30MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	SANOFI-AVENTIS AEBE SYNGROU AVENUE 348 BUILDING A KALITHEA 17676	ACTONEL OAW	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	SANOFI-AVENTIS AEBE SYNGROU AVENUE 348 BUILDING A KALITHEA 17677	ACTONEL 2 CONSECUTIVE DAYS PER MONTH	75MG/TAB	FILM COATED TABLET	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	SANOFI-AVENTIS AEBE SYNGROU AVENUE 348 BUILDING A KALITHEA 17678	RISEDRONATE / WINTHROP	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	ACTAVIS GROUP PTC EHF., ICELAND Reykjavikurvegur 76-78, 220, Hafnarfjordur Iceland	RISEDRONATE SODIUM / ACTAVIS	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	PNG GEROLYMATOS MEDICAL S.A. ASKLIPIOU 13 KRYONERI ATTIKIS 14568	MOTIVUS	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	DELEGANT HOLDINGS LTD, CYPRUS AGIAS ELENIS 36 COMMERCIAL CENTRE GALAXY 401 NICOSIA 1061 CYPRUS	RISELIB	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	S.J.A. PHARM Ltd ARKOLEON 11 10445 PATISSIA	DIFOSFON-S	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	ELPEN S.A. PHARMACEUTICAL INDUSTRY MARATHONOS AVENUE 95 PIKERMI 190 09	BONDAPEN	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	AURORA PHARMACEUTICALS A.E. EVROU 4 & MESSINIAS 2 GERAKAS 15344	BONMATE	35MG/TAB	FILM COATED TABLET	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
EL - Greece	GENERICS (U.K.) LTD - ENGLAND STATION CLOSE POTTERS BAR HERTS EN6 1TL ENGLAND	RISEDRONATE / GENERICS	35MG/TAB	FILM COATED TABLET	Oral use
EL - Greece	TEVA PHARMA B.V., UTRECHT, THE NETHERLANDS Computerweg 10, 3542 DR, Utrecht, The Netherlands	RISEDRONATE / TEVA	35MG/TAB	FILM COATED TABLET	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	ACTONEL 30 mg comprimidos recubiertos	30 mg	film coated tablets	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	ACTONEL 5 mg comprimidos recubiertos	5mg	film coated tablets	Oral use
ES - Spain	Warner Chilcott Iberia, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain	ACREL 5 mg comprimidos recubiertos con película	5 mg	film coated tablets	Oral use
ES - Spain	Warner Chilcott Iberia, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain	ACREL SEMANAL 35 mg comprimidos recubiertos con película	35mg	film coated tablets	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	ACTONEL SEMANAL 35 mg comprimidos recubiertos con película	35 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	ACTONEL 75 mg comprimidos recubiertos con película	75 mg	film coated tablets	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	LOSENTRA SEMANAL 35 mg comprimidos recubiertos con película	35 mg	film coated tablets	Oral use
ES - Spain	Warner Chilcott Iberia, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain	ACREL 75 mg comprimidos recubiertos con película	75 mg	film coated tablets	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	ACTONEL COMBI 35 mg comprimidos recubiertos con película + 1000 mg/880 UI granulado efervescente	35 mg + 1000 mg / 880 IU	film coated tablets	Oral use
ES - Spain	Warner Chilcott Iberia, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain	ACRELCOMBI 35mg comprimidos recubiertos con película+1000mg/880 UI granulado efervescente	35 mg + 1000 mg / 880 IU	film coated tablets and efervescent granules	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	Warner Chilcott Iberia, S.L. WTC Almeda Park, Ed. 1, 2ª pl. Plaça de la Pau s/n 08940 Cornellà de Llobregat (Barcelona) Spain	ACREL COMBI 35 mg + 500mg/400 UI comprimidos recubiertos con película	35 mg + 500 mg/400 UI	film coated tablets and efervescent granules	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plà, 2 08019 Barcelona	ACTONEL COMBI 35 mg + 500 mg/400 UI comprimidos recubiertos con película	35 mg + 500 mg/400 UI	film coated tablets	Oral use
ES - Spain	QUALIGEN, S.L.Avda. Barcelona, 69 08970Sant Joan Despi, Spain	RISEDRONATO SEMANAL QUALIGEN 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	RATIOPHARM ESPAÑA, S.A .Avda. de Burgos, 16 D - 5ª Planta 28036 Madrid	RISEDRONATO SEMANAL RATIOPHARM 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	MYLAN PHARMACEUTICALS, S.L. Plom 2-4, 5º Planta 08038 Barcelona	RISEMYL SEMANAL 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	TEVA GENERICOS ESPAÑOLA, S.L. Guzmán el Bueno 133, Edificio Britania 4ºIzq 28003 Madrid	MIOSEN SEMANAL 35 mg comprimidos recubiertos con película		film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ES - Spain	HEXAL PHARMA GMBH Carlberger Gasse, 44 A- 1235 Viena	RISEDRONATO SEMANTAL HEXAL 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	SANDOZ FARMACEUTICA, S.A. Avda. Osa Mayor, 4 28023 Aravaca (Madrid)	RISEDRONATO SEMANTAL SANDOZ 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	1A PHARMA GMBH Eduard Kittenberger Gasse, 56 A- 1235 Viena	RISEDRONATO SEMANTAL SALUTAS 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	LABORATORIO STADA, S.L. Frederic Mompou, 5 08960 Sant Just Desvern	RISEDRONATO SEMANTAL STADA 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	KERN PHARMA, S.L. Venus, 72. Poligono Industrial Colon II. 08228 Tarrasa	RISEDRONATO SEMANTAL KERN PHARMA 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	LABORATORIOS RANBAXY, S.L. Passeig de Gracia, 9 08007 Barcelona	RISEDRONATO SEMANTAL RANBAXY 35 mg comprimidos recubiertos con película		film coated tablets	Oral use
ES - Spain	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA, S.A. ul. Szkolna, 33 95-054 Ksawerow/Lodz	NORIFAZ 35 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA		film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ET - Estonia	Portfarma ehf Kollunarklettsvegur 2, 104 Reykjavik ICELAND	OSSINAT	5mg	Film-coated tablet	Oral use
ET - Estonia	Portfarma ehf Kollunarklettsvegur 2, 104 Reykjavik ICELAND	OSSINAT	35mg	Film-coated tablet	Oral use
ET - Estonia	Sanofi-Aventis Estonia OÜ Pärnu mnt 139E/2 11317 Tallinn ESTONIA	ACTONEL 35 MG OAW	35mg	Film-coated tablet	Oral use
ET - Estonia	Zentiva, k.s. UKabelovny 130 Dolni Mecholupy 102 37 Prague 10 CZECH REPUBLIC	RISENDROS 35MG	35mg	Film-coated tablet	Oral use
ET - Estonia	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjörður ICELAND	RISEDRONATE SODIUM ACTAVIS	35mg	Film-coated tablet	Oral use
ET - Estonia	ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm GERMANY	RIBIDRON	35mg	Film-coated tablet	Oral use
ET - Estonia	Sanofi-Aventis Estonia OÜ Pärnu mnt 139E/2 11317 Tallinn ESTONIA	ACTONEL	75mg	Film-coated tablet	Oral use
ET - Estonia	Zakład Farmaceutyczny Adamed Pharma S.A. 33 Szkolna Street, 95-054 Ksawerów POLAND	NORIFAZ	35mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
ET - Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht THE NETHERLANDS	RISONATE	35mg	Film-coated tablet	Oral use
ET - Estonia	Vale Pharmaceuticals Ltd 1B Gurtnafleur Business Park, Gurtnafleur, clonmel, Co. Tipperary IRELAND	RIGAT	35mg	Film-coated tablet	Oral use
FI - Finland	sanofi-Aventis Oy, Huopalahdentie 24, PL 22, 00350 Helsinki, Finland	Optinate	30 mg	film-coated tablet	Oral use
FI - Finland	sanofi-Aventis Oy, Huopalahdentie 24, PL 22, 00350 Helsinki, Finland	Optinate	5 mg	film-coated tablet	Oral use
FI - Finland	sanofi-Aventis Oy, Huopalahdentie 24, PL 22, 00350 Helsinki, Finland	Optinate Combi D	35 mg + 1000 mg / 880 IU	film-coated tablet and effervescent granules	Oral use
FI - Finland	sanofi-Aventis Oy, Huopalahdentie 24, PL 22, 00350 Helsinki, Finland	Optinate Septimum	35 mg	film-coated tablet	Oral use
FI - Finland	Ranbaxy (UK) Limited, Building 4, Chiswick Park, 566 Chiswick High Road, LONDON W4 5YE, United Kingdom	Risedronat Ranbaxy	35 mg	film-coated tablet	Oral use
FI - Finland	sanofi-Aventis Oy, Huopalahdentie 24, PL 22, 00350 Helsinki, Finland	Optinate	75 mg	film-coated tablet	Oral use
FI - Finland	Oy Leiras Finland Ab, PL 1406, 00101 Helsinki, Finland	Riseos	35 mg	film-coated tablet	Oral use
FI - Finland	ratiopharm GmbH, Graf- Arco-Strasse 3, 89079 Ulm, Germany	Riseratio	35 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FI - Finland	Mylan AB, BOX 23033, 10435 STOCKHOLM, Sweden	Vionate	35 mg	film-coated tablet	Oral use
FI - Finland	Actavis Group PTC ehf, Reykjavikurvegi 76-78, 220 HAFNARFJORDUR, Iceland	Risedronat Actavis	35 mg	film-coated tablet	Oral use
FI - Finland	Orifarm Generics A/S, Energivej 15, 5260 ODENSE S, Denmark	Risedronat Orifarm	30 mg	film-coated tablet	Oral use
FI - Finland	Orifarm Generics A/S, Energivej 15, 5260 ODENSE S, Denmark	Risedronat Orifarm	35 mg	film-coated tablet	Oral use
FI - Finland	Orifarm Generics A/S, Energivej 15, 5260 ODENSE S, Denmark	Risedronat Orifarm	5 mg	film-coated tablet	Oral use
FI - Finland	Sandoz A/S, C. F. Tietgens Boulevard 40, 5220 ODENSE SØ, Denmark	Risedronat Sandoz	35 mg	film-coated tablet	Oral use
FI - Finland	Stada Arzneimittel AG, Stadastrasse 2 - 18, 61118 BAD VILBEL, Germany	Risedronat Stada	35 mg	film-coated tablet	Oral use
FI - Finland	Stada Arzneimittel AG, Stadastrasse 2 - 18, 61118 BAD VILBEL, Germany	Risedronat Stada	5 mg	film-coated tablet	Oral use
FI - Finland	TEVA Sweden AB, Järnvägsgatan 11, BOX 1070, 25110 HELSINGBORG, Sweden	Risedronat Teva	35 mg	film-coated tablet	Oral use
FR - France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	RISEDRONATE ALMUS 35 mg, comprimé pelliculé	35 mg	tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	RISEDRONATE BGR 35 mg, comprimé pelliculé	35 mg	tablet	Oral use
FR - France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 Puteaux FRANCE	RISEDRONATE RANBAXY 35 mg, comprimé pelliculé	35 mg	tablet	Oral use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	RISEDRONATE WINTHROP 35 mg, comprimé pelliculé	35 mg	film-coated tablet	Oral use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	RISEDRONATE WINTHROP 75 mg, comprimé pelliculé	75 mg	film-coated tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONEL 30 mg, comprimé pelliculé	30 mg	film-coated tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONEL 35 mg, comprimé pelliculé	35 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONEL 5 mg, comprimé pelliculé	5 mg	film-coated tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONELCOMBI 35 mg + 1000 mg/880 UI, comprimé pelliculé et granulés effervescents	35 mg + 1000 mg/800 UI	film-coated tablet and effervescent granules	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONEL 75 mg, comprimé pelliculé	75 mg	tablet	Oral use
FR - France	Warner Chilcott France Immeuble "Le Jean Monnet" 11, Place des Vosges 92061 Paris La Défense Cedex France	ACTONELCOMBI 35 mg + 500 mg/400 UI, comprimé pelliculé	35 mg + 500 mg/400 UI	tablet	Oral use
HU - Hungary	Sanofi-aventis zrt. Tó u. 1-5. 1045 Budapest Hungary	ACTONEL 5 mg filmtabletta	5.00 mg Risedronate sodium (equivalent to 4.64 mg Risendronic acid)	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Sanofi-aventis zrt. Tó u. 1-5. 1045 Budapest Hungary	ACTONEL 35 mg filmtabletta	35.00 mg Risedronate sodium (equivalent to 32,5 mg Risendronic acid)	film-coated tablet	Oral use
HU - Hungary	Sanofi-aventis zrt. Tó u. 1-5. 1045 Budapest Hungary	ACTONEL TRIO 35 mg film- és rágótabletta	35.00 mg Risedronate sodium (equivalent to 69,6 mg Risendronic acid)	film-coated tablet and chewing tablet	Oral use
HU - Hungary	Sanofi-aventis zrt. Tó u. 1-5. 1045 Budapest Hungary	ACTONEL TRIO 75 mg film- és rágótabletta	75.00 mg Risedronate sodium (as Risendronic acid)	film-coated tablet and chewing tablet	Oral use
HU - Hungary	Vera Pharma Kft. Rákos köz 22. 1028 Budapest Hungary	BONEACT 35 mg filmtabletta	35.00 mg Risedronate sodium (as Risendronic acid)	film-coated tablet	Oral use
HU - Hungary	Vera Pharma Kft. Rákos köz 22. 1028 Budapest Hungary	BONEACT 755 mg filmtabletta	75.00 mg Risedronate sodium (as Risendronic acid)	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Aramis Pharma Kft. Mester u. 28. III/5. 1095 Budapest Hungary	NORIFAZ Trio 35 mg film- és rágótabletta	35,0 mgRisedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet and chewing tablet	Oral use
HU - Hungary	Zentiva k.s. Dolny Mecholupy, U kabelovny 130. 10237 Prague 10. Czech Republic	RISENDROS 35 mg filmtabletta	35,0 mg Risedronate sodium	film-coated tablet	Oral use
HU - Hungary	Vera Pharma Kft. Rákos köz 22. 1028 Budapest Hungary	RISETACT 35 mg filmtabletta	35,0 mg Risedronate sodium	film-coated tablet	Oral use
HU - Hungary	Sanofi-aventis zrt. Tó u. 1-5. 1045 Budapest Hungary	ACTONEL 75 mg filmtabletta	75.00 mg Risedronate sodium (equal to Risendronic acid)	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Ozone Laboratories BV 2 Martinus Nijhofflaan 2624 ES Delft Holland	JUVERITAL 5 mg filmtabletta	5,0 mgRisedronate sodium (equivalent to 5,74 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use
HU - Hungary	Ozone Laboratories BV 2 Martinus Nijhofflaan 2624 ES Delft Holland	JUVERITAL 35 mg filmtabletta	35,0 mgRisedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use
HU - Hungary	Aramis Pharma Kft. Mester u. 28. III/5. 1095 Budapest Hungary	NORIFAZ 35 mg filmtabletta	35,0 mgRisedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	GALEX d.d. Tisinška ulica 29g 9000 Murska Sobota Slovenia	RISEDRONAT GALEX 35 mg filmtabletta	35,0 mgRisedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use
HU - Hungary	Actavis Group PTC ehf. Reykjavikurvegur 76-78. 220 Hafnarfjordur Iceland	RISEDRONATE ACTAVIS 35 mg filmtabletta	35,0 mgRisedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use
HU - Hungary	Generics (UK) Ltd. Albany Gate, Darkes Lane, Potters bar EN61AG Hertfordshire UK	RISEDRONATE GENERICS (UK) 5 mg filmtabletta	5,0 mg Risedronate sodium (equivalent to 5,74 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
HU - Hungary	Generics (UK) Ltd. Albany Gate, Darkes Lane, Potters bar EN61AG Hertfordshire UK	RISEDRONATE GENERICS (UK) 35 mg filmtabletta	35,0 mg Risedronate sodium (equivalent to 40,17 mg Risedronate sodium hemipentahydr ate	film-coated tablet	Oral use
HU - Hungary	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	5 mg	Film-coated tablets	Oral use
HU - Hungary	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	35 mg	Film-coated tablets	Oral use
IE - Ireland	Rowex Ltd Bantry Co. Cork	Ridate Once a Week 35mg film-coated tablets	35 mg	film-coated tablets	Oral use
IE - Ireland	TEVA Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Risonate Once Weekly 35mg Film-Coated Tablets.	35mg	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel 5 mg film coated tablets	5mg	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel 30 mg film coated tablets	30mg	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel Once A Week 35 mg film-coated tablets	35mg	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel 75 Milligram Film Coated Tablets	75mg	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel Combi 35mg + 500mg film-coated tablets	35 mg + 1250 mg calcium	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel Plus Ca & D 35mg film-coated tablet + 1000mg/800 IU Effervescent Granules	35mg + 1000mg/880IU	film-coated tablets + effervescent granules	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Actonel Plus Ca & D Tablet 35mg and 500mg/400 IU Film- Coated Tablets.	35mg + (risedronate sodium) + 500mg/400UI	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Optinate Once a Week 35mg Film-coated Tablets	35mg	film-coated tablets	Oral use
IE - Ireland	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH United Kingdom	Optinate 75mg Film- coated Tablets	75mg	film-coated tablets	Oral use
IE - Ireland	Ranbaxy Ireland Ltd. Spafield, Cork Road, Cashel, Co. Tipperary Ranbaxy Ireland Ltd	Risedronate Sodium 35mg Once A Week Film-Coated Tablets	35mg	film-coated tablets	Oral use
IE - Ireland	Clonmel Healthcare Limited Waterford Road Clonmel Co. Tipperary Ireland	Risontel Once a week 35mg film-coated tablets	35 mg	film-coated tablets	Oral use
IE - Ireland	Actavis Group PTC ehf Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland Actavis Group PTC ehf	Risedronate Sodium Actavis 5 mg film-coated tablets	5 mg	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IE - Ireland	Actavis Group PTC ehf Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland Actavis Group PTC ehf	Risedronate Sodium Actavis 30 mg film-coated tablets	30 mg	film-coated tablets	Oral use
IE - Ireland	Actavis Group PTC ehf Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland Actavis Group PTC ehf	Risedronate Sodium Actavis 35 mg film-coated tablets	35 mg	film-coated tablets	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate	5 mg	Film-coated tablet	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate	30 mg	Film-coated tablet	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate	75 mg	Film-coated tablet	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate Combi	35 mg + 1250 mg calcium	film-coated tablets	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate Combi D	35 mg and 1000 mg/880 IU	film-coated tablet and effervescent granules	Oral use
IS - Iceland	Sanofi-aventis Norge AS, Strandveien 15 Box 133, 1325 Lysaker, Norway	Optinate Septimum	35 mg	film-coated tablet	Oral use
IS - Iceland	Portfarma ehf., Borgartúni 26, 105 Reykjavík, Iceland	Risedronat Sodium Portfarma	5 mg	Film-coated tablet	Oral use
IS - Iceland	Qualigen S.L., Avda. Barcelona 69 08970 , Sant Joan Despi, (Barcelona) Spain	Risedronat Qualigen	35 mg	Film-coated tablet	Oral use
IT - Italy	GRUPPO LEPETIT Srl VIALE LUIGI BODIO, 37/B 20158 Milano - Italy	OPTINATE	5 mg	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
IT - Italy	GRUPPO LEPETIT Srl VIALE LUIGI BODIO, 37/B 20158 Milano - Italy	OPTINATE	30 mg	film-coated tablets	Oral use
IT - Italy	GRUPPO LEPETIT Srl VIALE LUIGI BODIO, 37/B 20158 Milano - Italy	OPTINATE	35 mg	film-coated tablets	Oral use
IT - Italy	GRUPPO LEPETIT Srl VIALE LUIGI BODIO, 37/B 20158 Milano - Italy	OPTINATE	75 mg	film-coated tablets	Oral use
IT - Italy	SANOFI-AVENTIS SpA Viale L. Bodio, 37/B 20158 Milano	Risedronato Winthrop 5 mg compresse rivestite con film	5 mg	film-coated tablets	Oral use
IT - Italy	SANOFI-AVENTIS SpA Viale L. Bodio, 37/B 20158 Milano	Risedronato Winthrop 30 mg compresse rivestite con film	30 mg	film-coated tablets	Oral use
IT - Italy	SANOFI-AVENTIS SpA Viale L. Bodio, 37/B 20158 Milano	Risedronato Winthrop 35 mg compresse rivestite con film	35 mg	film-coated tablets	Oral use
IT - Italy	SANOFI-AVENTIS SpA Viale L. Bodio, 37/B 20158 Milano	Risedronato Winthrop 75 mg compresse rivestite con film	75 mg	film-coated tablets	Oral use
IT - Italy	WARNER CHILCOTT ITALY Srl Viale Giorgio Ribotta, 11 00144 Roma	ACTONEL	5 mg	film-coated tablets	Oral use
IT - Italy	WARNER CHILCOTT ITALY Srl Viale Giorgio Ribotta, 11 00144 Roma	ACTONEL	30 mg	film-coated tablets	Oral use
IT - Italy	WARNER CHILCOTT ITALY Srl Viale Giorgio Ribotta, 11 00144 Roma	ACTONEL	35 mg	film-coated tablets	Oral use
IT - Italy	WARNER CHILCOTT ITALY Srl Viale Giorgio Ribotta, 11	ACTONEL	75 mg	film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	00144 Roma				
IT - Italy	WARNER CHILCOTT ITALY Srl Viale Giorgio Ribotta, 11 00144 Roma	ACTOCALCIO D3	35 mg + 1000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
IT - Italy	SANOFI-AVENTIS SpA Viale L. Bodio, 37/B 20158 Milano	OPTICALCIO D3	35 mg + 1000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
LT - Lithuania	ZENTIVA, k.s., Ukabelovny 130 Dolní Měcholupy 102 37, Praha 10, Czechia	Risendros	35 mg	Film-coated tablet	Oral use
LT - Lithuania	UAB "SANOFI-AVENTIS LIETUVA", A.Juozapavičiaus g. 6/2 LT-09310 Vilnius, Lithuania	Actonel	35 mg	Film-coated tablet	Oral use
LT - Lithuania	UAB "SANOFI-AVENTIS LIETUVA", A.Juozapavičiaus g. 6/2 LT-09310 Vilnius, Lithuania	Actonel	5 mg	Film-coated tablet	Oral use
LT - Lithuania	Teva Pharma B.V., Computerweg 10 3542 DR Utrecht, The Netherlands	Risonate	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LT - Lithuania	Zakład Farmaceutyczny Adamed Pharma S.A, Ul. Szkolna 33, 95-054 Ksawerów, Poland	Norifaz	35 mg	Film-coated tablet	Oral use
LT - Lithuania	Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Islandia	Risedronate sodium Actavis	35 mg	Film-coated tablet	Oral use
LT - Lithuania	UAB "SANOFI-AVENTIS LIETUVA", A.Juozapavičiaus g. 6/2 LT-09310 Vilnius, Lithuania	Actonel	75 mg	Film-coated tablet	Oral use
LT - Lithuania	UAB "SANOFI-AVENTIS LIETUVA", A.Juozapavičiaus g. 6/2 LT-09310 Vilnius, Lithuania	Actonel	35 mg + 1000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
LT - Lithuania	ratiopharm GmbH, Graf- Arco-Strasse 3, Ulm D- 89079, Germany	Ribidron	35 mg	Film-coated tablet	Oral use
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	5 mg	Film-coated tablets	oral use
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	30mg	film-coated tablets	oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel	75mg	film-coated tablets	Oral use
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel Combi D	35 mg + 1000 mg/880 IU	film-coated tablets + effervescent granules	Oral use
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel Combi	35 mg + 1250 mg calcium	film-coated tablets	Oral use
LU - Luxembourg	Warner Chilcott Pharmaceuticals BVBA Pegasuslaan 5 1831 Diegem, Belgium	Actonel hebdomadaire	35mg	film-coated tablets	Oral use
LV - Latvia	Portfarma ehf, Köllunarklettsvegi 2, 104 Reykjavík, Iceland	Risedronate sodium Portfarma	5 mg	film-coated tablets	Oral use
LV - Latvia	Portfarma ehf, Köllunarklettsvegi 2, 104 Reykjavík, Iceland	Risedronate sodium Portfarma	35 mg	film-coated tablets	Oral use
LV - Latvia	Zentiva k.s., U kabelovny 130, Dolní Měcholupy, 102 37 Praha 10, Czech Republic	Risendros	35 mg	film-coated tablets	Oral use
LV - Latvia	sanofi-aventis Latvia SIA, Kr.Valdemara iela 33-8, Riga LV 1010, Latvia	Actonel Combi	35 mg + 1000 mg/880 IU	Film-coated tablets + effervescent	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
				granules	
LV - Latvia	sanofi-aventis Latvia SIA, Kr.Valdemara iela 33-8, Riga LV 1010, Latvia	Actonel OAW	35 mg	film-coated tablets	Oral use
LV - Latvia	Vale Pharmaceuticals Ltd., 1B Gurtnafleur Business Park, Gurtnafleur, Clonmel, Co. Tipperary, Ireland	Rigat	35 mg	film-coated tablets	Oral use
LV - Latvia	ratiopharm GmbH, Graf- Arco-Str.3, 89079 Ulm, Germany	Ribidron	35 mg	film-coated tablets	Oral use
LV - Latvia	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht, Netherlands	Risonate	35 mg	film-coated tablets	Oral use
LV - Latvia	Zakład Farmaceutyczny Adamed Pharma S.A., ul.Szkolna 33, 95-054 Ksawerow, Poland	Norifaz	35 mg	film-coated tablets	Oral use
LV - Latvia	Actavis Group PTC ehf., Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland	Risedronate Sodium Actavis	35 mg	film-coated tablets	Oral use
LV - Latvia	sanofi-aventis Latvia SIA, Kr.Valdemara iela 33-8, Riga LV 1010, Latvia	Actonel	75 mg	film-coated tablets	Oral use
MT - Malta	Sanofi-Aventis Malta Ltd, Triq Kan. K. Pirotta, Birkirkara, BKR 1114, Malta	Actonel	5mg	film-coated tablet	Oral use
MT - Malta	Sanofi-Aventis Malta Ltd, Triq Kan. K. Pirotta, Birkirkara, BKR 1114, Malta	Actonel	30mg	film-coated tablet	Oral use
MT - Malta	Sanofi-Aventis Malta Ltd, Triq Kan. K. Pirotta, Birkirkara, BKR 1114, Malta	Actonel Once a Week	35mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
MT - Malta	Beacon Pharmaceuticals Ltd 85 High Street Tunbridge Wells TN1 1YG United Kingdom	Risedronate 5mg film coated tablets	5mg	Tablets	Oral use
MT - Malta	Beacon Pharmaceuticals Ltd 85 High Street Tunbridge Wells TN1 1YG United Kingdom	Risedronate 30mg film coated tablets	30mg	Tablets	Oral use
MT - Malta	Beacon Pharmaceuticals Ltd 85 High Street Tunbridge Wells TN1 1YG United Kingdom	Risedronate 35mg film coated tablets	35mg	Tablets	Oral use
MT - Malta	Sanofi-Aventis Malta Ltd, Triq Kan. K. Pirotta, Birkirkara, BKR 1114, Malta	Actonel	75mg	film-coated tablet	Oral use
MT - Malta	Sanofi-Aventis Malta Ltd, Triq Kan. K. Pirotta, Birkirkara, BKR 1114, Malta	Actonel Plus Ca & D	35mg + 1000mg/880IU	film-coated tablet/effervesce nt granules	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actokit D, combinatieverpakking	35 mg + 1000 mg/880 IE	filmcoated tablets + effervescent granules	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actonel® 30 mg, filmomhulde tabletten	30 mg	filmcoated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actonel® 5 mg, filmomhulde tabletten	5 mg	filmcoated tablets	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actonel® Wekelijks 35 mg, filmomhulde tabletten	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actokit	35 mg + 1250 mg calcium	Film-coated tablets	Oral use
NL - Netherlands	Ranbaxy Belgium NV Leuvensestraat 28b 1800 Vilvoorde Belgium	Natriumrisedronaat 35 mg Ranbaxy	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Ceft Limited 65 Delamere Road, Hayes Middlesex UB4 0NN Belgium	Natriumrisedronaat Ceft 30 mg	30 mg	filmcoated tablets	Oral use
NL - Netherlands	Ceft Limited 65 Delamere Road, Hayes Middlesex UB4 0NN Belgium	Natriumrisedronaat Ceft 35 mg	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Ceft Limited 65 Delamere Road, Hayes Middlesex UB4 0NN Belgium	Natriumrisedronaat Ceft 5 mg	5 mg	filmcoated tablets	Oral use
NL - Netherlands	Sandoz B.V., Veluwezoom 22 1327 AH Almere Netherlands	Natriumrisedronaat Sandoz® wekelijks 35 mg	35 mg	filmcoated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NL - Netherlands	Centrafarm Services B.V. Nieuwe Donk 9 47879 AC Etten-Leur Netherlands	Risedronaatnatrium CF 30 mg	30 mg	filmcoated tablets	Oral use
NL - Netherlands	Centrafarm Services B.V. Nieuwe Donk 9 47879 AC Etten-Leur Netherlands	Risedronaatnatrium CF wekelijks 35 mg	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Centrafarm Services B.V. Nieuwe Donk 9 47879 AC Etten-Leur Netherlands	Risedronaatnatrium CF 5 mg	5 mg	filmcoated tablets	Oral use
NL - Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten Netherlands	Risedronaatnatrium Mylan 5 mg	5 mg	filmcoated tablets	Oral use
NL - Netherlands	Mylan B.V. Dieselweg 25 3752 LB Bunschoten Netherlands	Risedronaatnatrium Mylan Wekelijks 35 mg	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem Netherlands	Risedronaatnatrium Wekelijks 35 mg PCH	35 mg	filmcoated tablets	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	ActoCalD tabletten 35 mg + 500 mg / 400 IE filmomhulde tabletten, combinatieverpakking	35 mg + 500 mg / 400 IE	filmcoated tablets	Oral use
NL - Netherlands	Warner Chilcott Nederland BV Lichtenauerlaan 102-120 3062 ME Rotterdam Netherlands	Actonel® 75 mg, filmomhulde tabletten	75 mg	filmcoated tablets	Oral use
NO - Norway	Sanofi-aventis, Strandveien 15, 1366 Lysaker Norway	Optinate	5 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
NO - Norway	Sanofi-aventis, Strandveien 15, 1366 Lysaker Norway	Optinate	30 mg	Film-coated tablet	Oral use
NO - Norway	Sanofi-aventis, Strandveien 15, 1366 Lysaker Norway	Optinate Septimum	35 mg	Film-coated tablet	Oral use
NO - Norway	Orifarm Energivej 15, POB 69, DK-5260 Odense S Danmark	Risedronat Orifarm	5 mg	Film-coated tablet	Oral use
NO - Norway	Orifarm Energivej 15, POB 69, DK-5260 Odense S Danmark	Risedronat Orifarm	30 mg	Film-coated tablet	Oral use
NO - Norway	Orifarm Energivej 15, POB 69, DK-5260 Odense S Danmark	Risedronat Orifarm	35 mg	Film-coated tablet	Oral use
NO - Norway	Zakład Farmaceutyczny Adamed Pharma S.A., Szkolna Street 33, 95-054 Ksawerow, Poland	Norifaz	35 mg	Film-coated tablet	Oral use
NO - Norway	Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland	Risedronat Actavis	35 mg	Film-coated tablet	Oral use
NO - Norway	Teva Sweden AB, Box 1070, 25110 Helsingborg, Sweden	Risedronat Teva	35 mg	Film-coated tablet	Oral use
NO - Norway	Mylan AB, Box 23033, 10435 Stockholm, Sweden	Vionate	35 mg	Film-coated tablet	Oral use
PL - Poland	Sanofi-Aventis AB Gustavslundsvägen 139 Box 14142 167 14 BROMMA, Sweden	Actonel	5 mg	film coated tablets	Oral use
PL - Poland	Ranbaxy (Poland) Sp. z o.o. Kubickiego st. 11, 02-954 Warsaw, Poland	Resorpate	35 mg	film coated tablets	Oral use
PL - Poland	Sanofi-Aventis AB Gustavslundsvägen 139 Box 14142 167 14 BROMMA, Sweden	Actonel	30 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Sanofi-Aventis AB Gustavslundsvägen 139 Box 14142 167 14 BROMMA, Sweden	Actonel	35 mg	film coated tablets	Oral use
PL - Poland	ZENTIVA, k.s. U kabelovny 130, Dolní Měcholupy 102 37 Praga 10, Czech Republic	Risendros 35	35 mg	film coated tablets	Oral use
PL - Poland	Actavis Group PTC ehf. Reykjavíkurvegi 76-78 220 Hafnarfirdi, Iceland	Bifodron	35 mg	film coated tablets	Oral use
PL - Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St., 00-113, Warsaw, Poland	Nofemix	35 mg	film coated tablets	Oral use
PL - Poland	Zakład Farmaceutyczny Adamed Pharma S.A. Szkolna st. 33, 95-054 Ksawerów, Poland	Norifaz	35 mg	film coated tablets	Oral use
PL - Poland	Vale Pharmaceuticals Ltd 1G Gurtnafleur Business Park, Gurtnafleur, Clonmel, Co. Tipperary, Ireland	Rigat	35 mg	film coated tablets	Oral use
PL - Poland	ratiopharm GmbH Graf-Arco-Strasse 3, Ulm, 89073, Germany	Risedronat-ratiopharm	35 mg	film coated tablets	Oral use
PL - Poland	Labormed Pharma S.A. Bd. Theodor Pallady nr. 44B, sector 3, Bucharest, Romania	Juverital	5 mg	film coated tablets	Oral use
PL - Poland	Labormed Pharma S.A. Bd. Theodor Pallady nr. 44B, sector 3, Bucharest, Romania	Juverital	35 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PL - Poland	Galex d.d. Tišinska ul. 29g, 9000 Murska Sobota, Slovenia	Risedrolex 35 mg	35 mg	film coated tablets	Oral use
PT - Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park, Edifício 7 - 3º, 2740-244 Porto Salvo Portugal	Actonel	5 mg	Film-coated tablet	Oral use
PT - Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park, Edifício 7 - 3º, 2740-244 Porto Salvo Portugal	Actonel	30 mg	Film-coated tablet	Oral use
PT - Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park, Edifício 7 - 3º, 2740-244 Porto Salvo Portugal	Actonel 35 mg	35 mg	Film-coated tablet	Oral use
PT - Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park, Edifício 7 - 3º, 2740-244 Porto Salvo Portugal	Norsed	35 mg	Film-coated tablet	Oral use
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Risedronato de sódio Generis	5 mg	Film-coated tablet	Oral use
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Risedronato de sódio Generis	30 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Risedronato de sódio Generis	35 mg	Film-coated tablet	Oral use
PT - Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Lagoas Park, Edifício 5 A - Piso 2, 2740-298 Porto Salvo Portugal	Risedronato de sódio Mepha	35 mg	Film-coated tablet	Oral use
PT - Portugal	Bluepharma Genéricos - Comércio de Medicamentos, S.A. São Martinho do Bispo, 3045-016 Coimbra Portugal	Risedronato de sódio Bluepharma	35 mg	Film-coated tablet	Oral use
PT - Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, Sala 31, 1495-139 Miraflores - Algés Portugal	Risedronato de sódio Pharmakern	35 mg	Coated tablet	Oral use
PT - Portugal	GP - Genéricos Portugueses, Lda. Rua Henrique Paiva Couceiro, 29 - Venda Nova, 2700-451 Amadora Portugal	Risedronato de sódio GP	35 mg	Film-coated tablet	Oral use
PT - Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira, 2710-089 Sintra Portugal	Risedronato de sódio Farmoz	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto, 2830 Coina Portugal	Risedronato de sódio Alter	5 mg	Film-coated tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto, 2830 Coina Portugal	Risedronato de sódio Alter	30 mg	Film-coated tablet	Oral use
PT - Portugal	Alter, S.A. Estrada Marco do Grilo - Zemouto, 2830 Coina Portugal	Risedronato de sódio Alter	35 mg	Film-coated tablet	Oral use
PT - Portugal	Ranbaxy Portugal - Comércio e Desenvol. de Produtos Farmacêuticos, Unip., Lda. Rua do Campo Alegre, 1306, 3º - Sala 301/302 - Edifício Botânico, 4150-174 Porto Portugal	Risedronato de sódio Ranbaxy	35 mg	Film-coated tablet	Oral use
PT - Portugal	Solufarma - Produtos Farmacêuticos Unipessoal, Lda. Av. dos Bombeiros Voluntários, nº 146 - 1º, 2765-201 Estoril Portugal	Risedronato de sódio Riseflore	35 mg	Film-coated tablet	Oral use
PT - Portugal	Baldacci - Portugal, S.A. Rua Cândido de Figueiredo, 84-B, 1549-005 Lisboa Portugal	Risedronato de sódio Medilusa	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	ISUS - Produtos Farmacêuticos e Cosméticos, S.A. Rua António Quadros, 9G - Escritório 3, 1600-875 Lisboa Portugal	Risedronato de sódio Rizat	35 mg	Film-coated tablet	Oral use
PT - Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo, 3465-157 Santiago de Besteiros Portugal	Risedronato de sódio Labesfal	35 mg	Film-coated tablet	Oral use
PT - Portugal	Cinfa Portugal, Lda. Av. Tomás Ribeiro, 43 - Bloco 1, 4º B - Edifício Neopark, 2790-221 Carnaxide Portugal	Risedronato de sódio Cinfa	35 mg	Film-coated tablet	Oral use
PT - Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Atral	5 mg	Film-coated tablet	Oral use
PT - Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Atral	30 mg	Film-coated tablet	Oral use
PT - Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Atral	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Vida - Produtos Farmacêuticos, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Vida	5 mg	Film-coated tablet	Oral use
PT - Portugal	Vida - Produtos Farmacêuticos, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Vida	30 mg	Film-coated tablet	Oral use
PT - Portugal	Vida - Produtos Farmacêuticos, S.A. Rua da Estação, 42 - Vala do Carregado, 2600-726 Castanheira do Ribatejo Portugal	Risedronato de sódio Vida	35 mg	Film-coated tablet	Oral use
PT - Portugal	Decomed Farmacêutica, S.A. Rua Sebastião e Silva, 56, 2745-838 Massamá Portugal	Zectoel	5 mg	Film-coated tablet	Oral use
PT - Portugal	Decomed Farmacêutica, S.A. Rua Sebastião e Silva, 56, 2745-838 Massamá Portugal	Zectoel	30 mg	Film-coated tablet	Oral use
PT - Portugal	Decomed Farmacêutica, S.A. Rua Sebastião e Silva, 56, 2745-838 Massamá Portugal	Zectoel	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide Portugal	Risedronato de sódio Germed	5 mg	Film-coated tablet	Oral use
PT - Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide Portugal	Risedronato de sódio Germed	30 mg	Film-coated tablet	Oral use
PT - Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 - 1º Dto - Edifício Monsanto 2790-012 Portela de Carnaxide Portugal	Risedronato de sódio Germed	35 mg	Film-coated tablet	Oral use
PT - Portugal	Sanofi-Aventis - Produtos Farmacêuticos, S.A. Empreendimento Lagoas Park, Edifício 7 - 3º, 2740-244 Porto Salvo Portugal	Actonel	75 mg	Film-coated tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78, IS-220 Hafnarfjörður Islândia	Risedronato de sódio Actavis	35 mg	Film-coated tablet	Oral use
PT - Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada da Quinta, 148-148 A, Manique de Baixo 2645-436 Alcabideche Portugal	Norifaz	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda. Rua Quinta do Pinheiro - Edifício Tejo - 6º Piso, 2790- 143 Carnaxide Portugal	Risedronato de sódio Ratiopharm	35 mg	Film-coated tablet	Oral use
PT - Portugal	Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº, 1499-016 Algés Portugal	Risedronato de sódio Mylan	5 mg	Film-coated tablet	Oral use
PT - Portugal	Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº, 1499-016 Algés Portugal	Risedronato de sódio Mylan	35 mg	Film-coated tablet	Oral use
PT - Portugal	Qualigen, S.L. Avenida Barcelona, 69, Sant Joan Despí, 08970 Barcelona Espanha	Risedronato de sódio Qualigen	35 mg	Film-coated tablet	Oral use
PT - Portugal	Teva Pharma - Produtos Farmacêuticos, Lda. Edifício Cyprium, Av. 25 de Abril, 15, 2º F, 2795-195 Linda-a-Velha Portugal	Risedronato de sódio Teva	35 mg	Film-coated tablet	Oral use
PT - Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15, 2710- 693 Sintra Portugal	Risedronato de sódio Sandoz	35 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15, 2710- 693 Sintra Portugal	Risedronato de sódio 1APharma	35 mg	Film-coated tablet	Oral use
PT - Portugal	Ciclum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B, 2770-229 Paço de Arcos Portugal	Risedronato de sódio Ciclum	35 mg	Film-coated tablet	Oral use
PT - Portugal	Ciclum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B, 2770-229 Paço de Arcos Portugal	Risedronato de sódio Ciclum	5 mg	Film-coated tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78, IS-220 Hafnarfjörour Íslândia	Claronate	5 mg	Film-coated tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78, IS-220 Hafnarfjörour Íslândia	Claronate	30 mg	Film-coated tablet	Oral use
PT - Portugal	Actavis Group PTC ehf. Reykjavíkurvegi, 76-78, IS-220 Hafnarfjörour Íslândia	Claronate	35 mg	Film-coated tablet	Oral use
PT - Portugal	Arrow Generics, Ltd. Unit 2 - Eastman Way, SG1 4SZ Stevenage - Hertfordshire Reino Unido	Risedronato de sódio Arrow	35 mg	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Zaklad Farmaceutyczny Adamed Pharma S.A., Szkolna Street 33, 95-054 Ksawerow, Poland	Norifaz, 35 mg, comprimidos revestidos por pelicula	35 mg	film coated tablets	Oral use
RO - Romania	AVENTIS PHARMA AB Bryggvagen 16-18, 11768 Stockholm, Sweden	ACTONEL 5 mg film coated tablets	5 mg	film coated tablets	Oral use
RO - Romania	SANOFI-AVENTIS ROMÂNIA S.R.L. Str. Izvor, nr 80, etajele 6- 11, sector 5 Bucharest, Romania	ACTONEL SAPTAMANAL 35 mg film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	SANOFI-AVENTIS ROMÂNIA S.R.L. Str. Izvor, nr 80, etajele 6- 11, sector 5 Bucharest, Romania	ACTONEL 75 mg film coated tablets	75 mg	film coated tablets	Oral use
RO - Romania	TERAPIA SA Str. Fabricii nr. 124, Cluj- Napoca, Romania	OSODENS 35 mg film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	ZENTIVA, k.s. U kabelovny 130, Dolní Měcholupy 102 37 Praga 10, Czech Republic	RISENDROS 35 mg film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	Actavis Group PTC ehf Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Island	OSTEORON 35 mg film coated tablets	35 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
RO - Romania	Antibiotice S.A. Valea Lupului nr. 1, 707410 Iași, Romania	LORINE 35 mg film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	TEVA PHARMACEUTICALS S.R.L. Str. Domnița Ruxandra, nr. 12 parter, sector 2București, Romania	RISEDRONAT TEVA 35 mg film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	STADA Hemofarm SRL Zugrav Nedelcu nr.3, Timișoara, Romania	RISEDRONAT SODIC HF 35 mg, film coated tablets	35 mg	film coated tablets	Oral use
RO - Romania	LABORMED PHARMA S.A. Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	JUVERITAL 5 mg film coated tablets	5 mg	film coated tablets	Oral use
RO - Romania	LABORMED PHARMA S.A. Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	JUVERITAL 35 mg film coated tablets	35 mg	film coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
RO - Romania	Sanofi-aventis AB Gustavslundsvägen 139, Box 141 42, 167 14 Bromma, Sweden	ACTONEL COMBI D 35 mg + 500 mg/400 UI film coated tablets	35 mg + 500 mg/400 UI	film coated tablets	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan	5 mg	film-coated tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan	30 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate	5 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate	30 mg	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra	5 mg	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra	30 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed	5 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed	30 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate Septimum	35 mg	film-coated tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan Septimum	35 mg	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra Septimum	35 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed Septimum	35 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate Combi	35 mg + 1250 mg calcium	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra Combi	35 mg + 1250 mg calcium	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed Combi	35 mg + 1250 mg calcium	film-coated tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan Combi	35 mg + 1250 mg calcium	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate Combi D	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan Combi D	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra Combi D	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed Combi D	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate	75 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed	75 mg	film-coated tablet	Oral use
SE - Sweden	Sanofi-aventis S.p.A. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Norsed Combi D	35 mg + 500 mg/400 IE	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra Combi D	35 mg + 500 mg/400 IE	film-coated tablet	Oral use
SE - Sweden	Ranbaxy (UK) Ltd 3rd floor, CP house 97-107, Uxbridge Road Ealing, London W5 5TL United Kingdom	Risedronate Ranbaxy	35 mg	film-coated tablet	Oral use
SE - Sweden	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Danmark	Risedronat Sandoz	35 mg	film-coated tablet	Oral use
SE - Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Risedronat Orifarm	5 mg	film-coated tablet	Oral use
SE - Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Risedronat Orifarm	30 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SE - Sweden	Orifarm Generics A/S Energivej 15 POB 69 DK-5260 Odense S Denmark	Risedronat Orifarm	35 mg	film-coated tablet	Oral use
SE - Sweden	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	Riseratio	35 mg	film-coated tablet	Oral use
SE - Sweden	Teva Sweden AB Box 1070 251 10 Helsingborg Sweden	Risedronat Teva	35 mg	film-coated tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan	75 mg	film-coated tablet	Oral use
SE - Sweden	Gruppo LePetit S.r.l. Viale Luigi Bodio 37/b IT-20158 Milano Italy	Avestra	75 mg	film-coated tablet	Oral use
SE - Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Optinate Combi D	35 mg + 500 mg/400 IE	film-coated tablet	Oral use
SE - Sweden	Warner Chilcott UK Limited Old Belfast Road Millbrook Larne County Antrim BT40 2SH, United Kingdom	Fortipan Combi D	35 mg + 500 mg/400 IE	film-coated tablet	Oral use
SE - Sweden	Zakład Farmaceutyczny Adamed Pharma S.A., ul. Szkolna 33 95-054 Ksawerów , Polen	Risedronat Adamed Pharma	35 mg	film-coated tablet	Oral use
SI - Slovenia	Sanofi-aventis d.o.o., Dunajska cesta 151, SI- 1000 Ljubljana	Actonel 30 mg filmsko obložene tablete	30 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SI - Slovenia	Sanofi-aventis d.o.o., Dunajska cesta 151, SI- 1000 Ljubljana	Actonel 5 mg filmsko obložene tablete	5 mg	film-coated tablet	Oral use
SI - Slovenia	Sanofi-aventis d.o.o., Dunajska cesta 151, SI- 1000 Ljubljana	Actonel 75 mg filmsko obložene tablete	75 mg	film-coated tablet	Oral use
SI - Slovenia	Sanofi-aventis d.o.o., Dunajska cesta 151, SI- 1000 Ljubljana	Actonel enkrat tedensko 35 mg filmsko obložene tablete	35 mg	film-coated tablet	Oral use
SI - Slovenia	Sanofi-aventis d.o.o., Dunajska cesta 151, SI- 1000 Ljubljana	Actonel Combi D	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use
SI - Slovenia	Galex, d.d., Tišinska ulica 29g, Murska Sobota, Slovenia	Riserdonat Galex 35 mg filmsko obložene tablete	35 mg	film-coated tablet	Oral use
SK - Slovakia	STADA Arzneimittel AG Stadastrasse 2-18 Bad Vilbel, 61118 Germany	Risedronat STADA 35 mg	35 mg	Film coated tablet	Oral use
SK - Slovakia	Actavis Group PTC ehf Dalshraun 1 220 Hafnarfjordur Iceland	Bifodron 35 mg	35 mg	Film coated tablet	Oral use
SK - Slovakia	Zakład Farmaceutyczny Adamed Pharma SA 33 Szkolna Street Ksawerów, 95-054 Poland	Norifaz 35 mg	35 mg	Film coated tablet	Oral use
SK - Slovakia	Gedeon Richter Plc. Gyômrôi út 19-21 1103, Budapest Hungary	Nurrid 35 mg	35 mg	Film coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
SK - Slovakia	ZENTIVA, k.s. U kabelovny 130, Dolní Měcholupy 102 37 Praga 10, Czech Republic	RISENDROS 35 mg - TBL FLM	35 mg	film-coated tablets	Oral use
SK - Slovakia	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	5 mg	Film-coated tablets	Oral use
SK - Slovakia	LABORMED-PHARMA S.A., Theodor Pallady Boulevard 44B, Sector 3, RO-032266 Bucharest, Romania	Juverital	35 mg	Film-coated tablets	Oral use
SK - Slovakia	Sanofi-aventis Slovakia s.r.o. Einsteinova 24 SK – 851 01 BRATISLAVA	ACTONEL 5 MG	5 mg	Film coated tablet	Oral use
SK - Slovakia	Sanofi-aventis Slovakia s.r.o. Einsteinova 24 SK – 851 01 BRATISLAVA	ACTONEL 75MG	75 mg	Film coated tablet	Oral use
SK - Slovakia	Sanofi-aventis Slovakia s.r.o. Einsteinova 24 SK – 851 01 BRATISLAVA	ACTONEL COMBI	35 mg + 500 mg/400 UI	film coated tablets	Oral use
SK - Slovakia	TEVA Pharmaceuticals Slovakia s.r.o., Teslova 26, 82102 Bratislava, Slovak Republic	Risedronat Teva 35 mg filmom obalené tablety	35mg	Film coated tablet	Oral use
UK - United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
UK - United Kingdom	Sandoz Limited, 37 Woolmer Way, Bordon, Hampshire GU35 9QE	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL	Risedronate sodium 5mg tablets	5mg	film-coated tablet	Oral use
UK - United Kingdom	Generics (UK) Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel 5mg Tablets	5mg`	film-coated tablet	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel 30mg Tablets	30mg	film-coated tablet	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel Once a Week 35mg Tablet	35mg	film-coated tablet	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel Combi 35 mg film-coated tablets + 1000 mg / 880 IU effervescent granules	35 mg + 1000 mg/880 IE	film-coated tablet and effervescent granules	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel 75mg tablet	75mg	film-coated tablet	Oral use
UK - United Kingdom	Warner Chilcott UK Limited, Old Belfast Road, Millbrook, Larne, Co. Antrim BT40 2SH, UK	Actonel Combi 35 mg + 500 mg / 400 IU film-coated tablets	35 mg + 500 mg/400 UI	film-coated tablet	Oral use
UK - United Kingdom	Winthrop Pharmaceuticals UK Ltd, One Onslow Street, Guildford, Surrey, GU1 4YS,	Norsed Once a Week	35mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	UK				
UK - United Kingdom	Ranbaxy (UK) Limited, 95 Park Lane, Mayfair. London W1K 7TE, United Kingdom	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Ratiopharm GmbH, 5 Jackson Close, Grove Road, Cosham, Portsmouth, Hampshire, PO6 1UP	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Pharmathen SA, 6 Dervenakion Street, Pallini, Athens, GR-153 51, Greece	Risedronate sodium 5mg tablets	5mg	film-coated tablet	Oral use
UK - United Kingdom	Pharmathen SA, 6 Dervenakion Street, Pallini, Athens, GR-153 51, Greece	Risedronate sodium 30mg tablets	30mg	film-coated tablet	Oral use
UK - United Kingdom	Pharmathen SA, 6 Dervenakion Street, Pallini, Athens, GR-153 51, Greece	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Beacon Pharmaceuticals Ltd, 85 High Street, Tunbridge Wells, Kent TN1 1YG, UK	Risedronate sodium 5mg tablets	5mg	film-coated tablet	Oral use
UK - United Kingdom	Beacon Pharmaceuticals Ltd, 85 High Street, Tunbridge Wells, Kent TN1 1YG, UK	Risedronate sodium 30mg tablets	30mg	film-coated tablet	Oral use
UK - United Kingdom	Beacon Pharmaceuticals Ltd, 85 High Street, Tunbridge Wells, Kent TN1 1YG, UK	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use
UK - United Kingdom	Zakład Farmaceutyczny Adamed Pharma SA, ul. Szkolna 33, 95-054 Ksawerow, Poland	Norifaz 35mg tablet	35mg	film-coated tablet	Oral use
UK - United Kingdom	Apotex Europe BV, Darwinweg 20, 2333 C R Leiden, The Netherlands	Risedronate sodium 35mg tablets	35mg	film-coated tablet	Oral use

Tiludronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
BE - Belgium	Sanofi-Aventis Belgium NV Culliganlaan 1C 1831 Diegem Belgium	Skelid	200 mg	Tablets	Oral use
ES - Spain	SANOFI AVENTIS, S.A.Josep Plá, 2 08019 Barcelona	SKELID 200 mg comprimidos	200mg	tablets	Oral use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	ACIDE TILUDRONIQUE SANOFI PHARMA 200 mg, comprimé	200 mg	tablet	Oral use
FR - France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	SKELID 200 mg, comprimé	200 mg	tablet	Oral use
LU - Luxembourg	Sanofi-Aventis Belgium NV Culliganlaan 1C 1831 Diegem Belgium	Skelid	200 mg	Tablets	Oral use
UK - United Kingdom	Sanofi-Synthelabo Limited, One Onslow Street, Guildford, Surrey GU1 4YS, UK	Skelid	200 mg	tablet	Oral use

Ibandronic acid containing medicinal products with Marketing Authorisation in the European Union

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
DE - Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt	Ibandronsäure dura 150 mg Filmtabletten	169,32 mg	Film-coated tablet	Oral use
DE - Germany	Orifarm Generixs A/S Energivej 15 DK-7260 ODENSE S Denmark	Ibandronat Orifarm 50 mg Filmtabletten	65,4 mg	Film-coated tablet	Oral use
DK - Denmark	Pharmathen S.A., 6, Dervenakion str., GR-15351 Pallini Attiki, Greece	Baxogar	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Gedeon Richter Plc., Gyömrői út 19-21, HU-1103 Budapest, Hungary	Etanorden	50 mg	Filmcoated- tablets	Oral use
DK - Denmark	Gedeon Richter Plc., Gyömrői út 19-21, HU-1103 Budapest, Hungary	Etanorden	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Mylan AB, Postbox 230 33, Ynglingagatan 14, Se-104 35 Stockholm, Sweden	IbamyI	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Actavis Group PTC ehf., Postbox 425, Reykjavíkurvegi 76-78, IS- 220 Hafnarfjörður, Iceland	Ibandronat "Actavis"	50 mg	Filmcoated- tablets	Oral use
DK - Denmark	Actavis Group PTC ehf., Postbox 425, Reykjavíkurvegi 76-78, IS- 220 Hafnarfjörður, Iceland	Ibandronat "Actavis"	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Arrow ApS, Hovedgaden 41, 2, DK-2970 Hørsholm, Denmark	Ibandronate "Arrow"	150 mg	Tablets	Oral use
DK - Denmark	Orifarm Generics A/S, Postbox 69, Energivej 15, DK-5260 Odense S,	Ibandronate "Orifarm"	50 mg	Filmcoated- tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
	Denmark				
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Ibandronate "ratiopharm"	50 mg	Filmcoated- tablets	Oral use
DK - Denmark	ratiopharm GmbH, Graf- Arco-Strasse 3, DE-89079 Ulm, Germany	Ibandronate "ratiopharm"	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Pharmathen S.A., 6, Dervenakion str., GR-15351 Pallini Attiki, Greece	Quodixor	150 mg	Filmcoated- tablets	Oral use
DK - Denmark	Orifarm Generics A/S, Postbox 69, Energivej 15, DK-5260 Odense S, Denmark	Ibandronate "Orifarm"	50 mg	Filmcoated- tablets	Oral use
FI - Finland	Arrow Pharma ApS, Hovedgaden 41. 2. sal, 2970 HØRSHOLM, Denmark	Ibandronate Arrow	150 mg	tablet	Oral use
FI - Finland	Orifarm Generics A/S, Energivej 15, 5260 ODENSE S, Denmark	Ibandronate Orifarm	50 mg	film-coated tablet	Oral use
FI - Finland	Ratiopharm GmbH, Graf- Arco-Strasse 3, 89079 Ulm, Germany	Ibandronate ratiopharm	150 mg	film-coated tablet	Oral use
FI - Finland	Ratiopharm GmbH, Graf- Arco-Strasse 3, 89079 Ulm, Germany	Ibandronate ratiopharm	50 mg	film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FI - Finland	Gedeon Richter Plc, Gyömrői út 19-21, 1103 Budapest, Hungary	Etanorden	150 mg	film-coated tablet	Oral use
FI - Finland	Mylan AB, BOX 23033, 10435 STOCKHOLM, Sweden	Ibamyl	150 mg	film-coated tablet	Oral use
FR - France	GEDEON RICHTER Gyömrői út 19-21 1103 Budapest X HONGRIE	KALOSSO 50 mg, comprimé pelliculé	50 mg	tablet	Oral use
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	ACIDE IBANDRONIQUE MYLAN 150 mg, comprimé pelliculé	150 mg	tablet	Oral use
FR - France	GEDEON RICHTER Gyömrői út 19-21 1103 Budapest X HONGRIE	ETANORDEN 150 mg, comprimé pelliculé	150 mg	tablet	Oral use
FR - France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	IBANDROMYLAN 150 mg, comprimé pelliculé	150 mg	tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
FR - France	GEDEON RICHTER Gyömroi ut 19-21 1103 Budapest X HONGRIE	KALOSSO 150 mg, comprimé pelliculé	150 mg	tablet	Oral use
IS - Iceland	Portfarma ehf., Borgartúni 26, 105 Reykjavík, Iceland	Zivetenó	150 mg	Film-coated tablet	Oral use
LT - Lithuania	Gedeon Richter Plc., 1103 Budapest Gyömrői út 19-21, Hungary	Etanorden	150 mg	Film-coated tablet	Oral use
PT - Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4 - Piso 1, Escrit. 8, 2710-444 Sintra Portugal	Ácido Ibandrónico Generis	150 mg	Film-coated tablets	Oral use
PT - Portugal	Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Lagoas Park, Edifício 5 A - Piso 2, 2740-298 Porto Salvo Portugal	Ácido ibandrónico Ombene	150 mg	Film-coated tablets	Oral use
PT - Portugal	Optimal Regulatory Solutions, S.L. Via Augusta, 59, 08006 Barcelona Espanha	Ácido ibandrónico Orsfelt	150 mg	Film-coated tablets	Oral use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
PT - Portugal	Cicum Farma Unipessoal, Lda. Quinta da Fonte, Rua Vitor Câmara, 2 - Edifício D. Amélia, Piso 1, Ala B, 2770-229 Paço de Arcos Portugal	Ácido ibandrónico Cicum	150 mg	Film-coated tablets	Oral use
PT - Portugal	Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, Sala 31, 1495-139 Miraflores - Algés Portugal	Ácido Ibandrónico Pharmakern	150 mg	Film-coated tablets	Oral use
PT - Portugal	Gedeon Richter, Plc. Gyömrői út, 19-21, H-1103 Budapest Hungria	Etanorden	150 mg	Film-coated tablets	Oral use
PT - Portugal	Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº, 1499-016 Álgés Portugal	Ácido Ibandrónico Mylan	150 mg	Film-coated tablets	Oral use
PT - Portugal	Arrow ApS Hovedgaden 41, 2, 2970 Horsholm Dinamarca	Ácido Ibandrónico Arrow	150 mg	Tablets	Oral use
PT - Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15, 2710- 693 Sintra Portugal	Ácido Ibandrónico Sandoz	150 mg	Film-coated tablets	Oral use