1 December 2016
EMA/806387/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: risedronate

Procedure no.: PSUSA/00002648/201603

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ACTONEL® OAW/«μία φορά την εβδομάδα» 35 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/003	19723	ACTAVIS GROUP PTC EHF.	CY
Actonel 30 mg comprimidos recubiertos con película	SE/H/0192/002	63.207	ACTAVIS GROUP PTC EHF.	ES
Actonel 5 mg comprimidos recubiertos con película	SE/H/0192/001	63.208	ACTAVIS GROUP PTC EHF.	ES
Actonel 75 mg comprimidos recubiertos con película	SE/H/0192/005	69.696	ACTAVIS GROUP PTC EHF.	ES
Actonel Semanal 35 mg comprimidos recubiertos con película	SE/H/0192/003	65167	ACTAVIS GROUP PTC EHF.	ES
Optinate Septimum 35 mg kalvopäällysteiset tabletit	SE/H/0192/003	17654	ACTAVIS GROUP PTC EHF.	FI
Risedronate Warner Chilcott 75 mg, comprimé pelliculé	SE/H/0194	NL38228	ACTAVIS GROUP PTC EHF.	FR
Actonel Combi D 35 mg + 1000 mg / 880 IU filmom obložene tablete + šumeće granule	not available	UP/I-530-09/13-02/180	ACTAVIS GROUP PTC EHF.	HR
Actonel 35 mg filmom obložene tablete	not available	HR-H-350046678	ACTAVIS GROUP PTC EHF.	HR
Actonel 35 mg filmtabletta	SE/H/0192/003	OGYI-T- 8738/01	ACTAVIS GROUP PTC EHF.	HU
Optinate Septimum 35 mg filmuhúðaðar töflur.	SE/H/0192/003	IS/1/03/043/01	ACTAVIS GROUP PTC EHF.	IS
Actocalcio D3 35 mg+1000 mg/800 UI	SE/H/0959/001	040352015M	ACTAVIS GROUP PTC EHF.	IT

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Optinate	SE/H/0195/001	0345700	ACTAVIS GROUP PTC EHF.	IT
Optinate	SE/H/0195/002	034570	ACTAVIS GROUP PTC EHF.	IT
Optinate	SE/H/0195/003	0345701	ACTAVIS GROUP PTC EHF.	IT
Actonel Combi 35 mg plevele dengtos tabletes + 1 000 mg / 880 TV šnypščiosios granules	SE/H/0732/001	LT/1/07/0827/001	ACTAVIS GROUP PTC EHF.	LT
Actonel Once a Week 35 mg film-coated tablets.	SE/H/0192/003	MA628/14201	ACTAVIS GROUP PTC EHF.	MT
Actonel Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 IU effervescent granules	SE/H/0732/001	MA628/14202	ACTAVIS GROUP PTC EHF.	MT
Optinate Septimum 35 mg filmdrasjerte tabletter	not available	01-13110	ACTAVIS GROUP PTC EHF.	NO
Avestra 5 mg film-coated tablets	SE/H/0195/001	15292	ACTAVIS GROUP PTC EHF.	SE
Avestra 75 mg film coated tablets.	SE/H/0195/003	24568	ACTAVIS GROUP PTC EHF.	SE
Avestra Septimum 35 mg film-coated tablets.	SE/H/0195/002	17859	ACTAVIS GROUP PTC EHF.	SE
Norsed Combi D 35 mg + 1000 mg / 880 IE filmdragerade tabletter + brusgranulat	SE/H/0959/001	22394	ACTAVIS GROUP PTC EHF.	SE
Norsed Septimum, 35 mg, filmcoated tablets	SE/H/0194	17860	ACTAVIS GROUP PTC EHF.	SE
Norsed, 75 mg, filmcoated tablets	SE/H/0194	24567	ACTAVIS GROUP PTC EHF.	SE

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Optinate 30 mg film-coated tablets	SE/H/0192/002	15297	ACTAVIS GROUP PTC EHF.	SE
Optinate 5 mg film-coated tablets	SE/H/0192/001	15296	ACTAVIS GROUP PTC EHF.	SE
Optinate Combi 35 mg + 500 mg film-coated tablets	SE/H/0192/004	19776	ACTAVIS GROUP PTC EHF.	SE
Optinate Combi D 35mg + 1000mg/880 IE filmdragerade tabletter + brusgranulat	SE/H/0732/001	22391	ACTAVIS GROUP PTC EHF.	SE
Optinate Septimum 35 mg filmdragerade tabletter.	SE/H/0192/003	17857	ACTAVIS GROUP PTC EHF.	SE
Optinate, 75 mg, filmcoated tablets	SE/H/0192/005	24565	ACTAVIS GROUP PTC EHF.	SE
Actonel 75 mg filmsko obložene tablete	SE/H/0192/005	H/08/00115/001	ACTAVIS GROUP PTC EHF.	SI
Actonel Combi 35 mg + 1.000 mg / 880 i.e. filmsko obložene tablete + šumeča zrnca	SE/H/0732/001	H/07/01913/001	ACTAVIS GROUP PTC EHF.	SI
Acrel 5 mg comprimidos recubiertos con película	SE/H/0193/001	66.952	ACTAVIS PHARMA IBERIA, SLU	ES
Acrel 75 mg comprimidos recubiertos con película	SE/H/0192/005	69.786	ACTAVIS PHARMA IBERIA, SLU	ES
Acrel Semanal 35 mg comprimidos recubiertos con película	SE/H/0193/003	65.906	ACTAVIS PHARMA IBERIA, SLU	ES

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Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835098/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835100/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835112/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835124/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835136/M	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003/MR	040835148	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedron-HEXAL 75 mg Filmtabletten	NL/H/2054/001	82270.00.00	HEXAL AG	DE
RISEBONE DUO	not available	OGYI-T-22651/01	PHARMA PATENT KFT.	HU
RISEBONE DUO MAX	not available	OGYI-T-22651/02	PHARMA PATENT KFT.	HU
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 401-5	SANOFI-AVENTIS FRANCE	FR
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 407-3	SANOFI-AVENTIS FRANCE	FR
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 406-7	SANOFI-AVENTIS FRANCE	FR
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 404-4	SANOFI-AVENTIS FRANCE	FR

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 402-1	SANOFI-AVENTIS FRANCE	FR
RISEDRONATE ZENTIVA 35 MG, COMPRIME PELLICULE	SE/H/0194/003	353 403-8	SANOFI-AVENTIS FRANCE	FR
ACTONEL® «2 συνεχόμενες ημέρες το μήνα» 75 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/005	73038/001-12-2014	SPECIFAR S.A.	GR
ACTONEL® 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/002	68871/01-12-2014	SPECIFAR S.A.	GR
ACTONEL® OAW/«μία φορά την εβδομάδα» 35 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/003	81506/01-12-2014	SPECIFAR S.A.	GR
Actonel® 30 mg Filmtabletten	SE/H/0192/002	48671.01.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel® 5 mg Filmtabletten	SE/H/0192/001	48671.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel® 75 mg Filmtabletten	SE/H/0192/005/DC	67799.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel® einmal wöchentlich 35 mg Filmtabletten	SE/H/0192/003	55437.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel® plus Calcium 35 mg + 500 mg Filmtabletten	SE/H/0192/004	61308.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Actonel® plus Calcium 35 mg + 500 mg Filmtabletten	SE/H/0192/004	61308.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel® plus Calcium D 35 mg + 1000 mg/880 I.E Filmtabletten + Brausegranulat	SE/H/0732/001/MR	68222.00.00	WARNER CHILCOTT DEUTSCHLAND GMBH	DE
Actonel 30 mg, comprime pellicule	SE/H/192/002/MR	354 365-2 ,354 366-9, 354 367-5, 562 710-0	WARNER CHILCOTT FRANCE	FR
Actonel 35 mg, comprime pellicule	SE/H/192/003/MR	361 577-1; 366 668-5	WARNER CHILCOTT FRANCE	FR
Actonel 5 mg comprime pellicule	SE/H/192/001/MR	354 361-7, 562 709-2, 354 362-3, 354 364-6, 562 708-6	WARNER CHILCOTT FRANCE	FR
Actonel 75 mg comprime pellicule	SE/H/192/05/DC	384 568-9, 384 569-5, 384 570-3, 384-572-6	WARNER CHILCOTT FRANCE	FR
ACTONELCOMBI 35 mg +1000 mg/880 UI, comprime pellicule et granules effervescents	SE/H/732/001/MR	381 303-4, 381 304-0, 381 305-7, 382 845-5, 571 238-9	WARNER CHILCOTT FRANCE	FR
Acrel 35 mg comprimidos recubiertos con pelicula	SE/H/193/003/MR	65,906	WARNER CHILCOTT IBERIA, S.L.	ES
Acrel 5 mg comprimidos recubiertos con pelicula	SE/H/0193/001	66.952	WARNER CHILCOTT IBERIA, S.L.	ES
Acrel 75 mg comprimidos recubiertos con pelicula	SE/H/0193/005	69.786	WARNER CHILCOTT IBERIA, S.L.	ES
Actonel 30 mg compresse rivestite con film	SE/H/192/002/MR	034568067;034568079	WARNER CHILCOTT ITALY S.R.L.	IT

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Actonel 35 mg compresse rivestite con film	SE/H/192/003/MR	034568081;034568093; 034568105;034568117; 034568129;034568131	WARNER CHILCOTT ITALY S.R.L.	IT
Actonel 5 mg compresse rivestite con film	SE/H/192/001/MR	034568016;034568028; 034568030;034568042; 034568055	WARNER CHILCOTT ITALY S.R.L.	IT
Actonel 75mg compresse rivestite con film	SE/H/192/05/DC	034568143;034568156; 034568168;034568170	WARNER CHILCOTT ITALY S.R.L.	IT
Actokit D, combinatieverpakking	SE/H/732/001/MR	RVG 34894	WARNER CHILCOTT NEDERLAND B.V.	NL
Actokit, combinatieverpakking, filmomhulde tabletten	SE/H/192/004/MR	RVG 31634	WARNER CHILCOTT NEDERLAND B.V.	NL
Actonel 30 mg filmomhulde tabletten	SE/H/0192/002	RVG 24990	WARNER CHILCOTT NEDERLAND B.V.	NL
Actonel 5 mg filmomhulde tabletten	SE/H/0192/001	RVG 25801	WARNER CHILCOTT NEDERLAND B.V.	NL
Actonel 75 mg, filmomhulde tabletten	SE/H/0192/005	RVG34632	WARNER CHILCOTT NEDERLAND B.V.	NL
Actonel Wekelijks 35 mg, filmomhulde tabletten	SE/H/0192/003	RVG 28338	WARNER CHILCOTT NEDERLAND B.V.	NL
Actonel 30 mg, filmomhulde tabletten	SE/H/0192/002	BE212247	WARNER CHILCOTT PHARMACEUTICALS BVBA	BE

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Actonel 35 mg Wekelijks, filmomhulde tabletten	SE/H/0192/003	BE244535	WARNER CHILCOTT PHARMACEUTICALS BVBA	BE
Actonel 5 mg filmomhulde tabletten	SE/H/0192/001	BE212231	WARNER CHILCOTT PHARMACEUTICALS BVBA	BE
Actonel 75 mg filmomhulde tabletten	SE/H/0192/005	BE315472	WARNER CHILCOTT PHARMACEUTICALS BVBA	BE
Actonel Combi D 35 mg + 1000 mg / 880 IE filmomhulde tabletten + bruisgranulaat	SE/H/732/001/MR	BE304683	WARNER CHILCOTT PHARMACEUTICALS BVBA	BE
Actonel 30 mg comprimes pellicules	SE/H/0192/002	0643/00/06/0020	WARNER CHILCOTT PHARMACEUTICALS BVBA	LU
Actonel 35 mg hebdomadaire comprimes pellicules	SE/H/0192/003	0643/03/02/0038	WARNER CHILCOTT PHARMACEUTICALS BVBA	LU
Actonel 5 mg comprimes pellicules	SE/H/0192/001	0643/00/06/0021	WARNER CHILCOTT PHARMACEUTICALS BVBA	LU
Actonel 75 mg comprimes pellicules	SE/H/0192/005	0643/09010027	WARNER CHILCOTT PHARMACEUTICALS BVBA	LU
Actonel Combi D 35 mg + 1000 mg / 880 UI, comprimes pellicules and granules effervescents	SE/H/732/001/MR	0643/08/04/0038	WARNER CHILCOTT PHARMACEUTICALS BVBA	LU
Actonel 30 mg film-coated tablets	SE/H/192/002	PA 1635/1/2	WARNER CHILCOTT UK LIMITED	IE
Actonel 5 mg film-coated tablets	SE/H/0192/001	PA 1635/1/1	WARNER CHILCOTT UK LIMITED	IE

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Actonel 75 mg film-coated tablets	SE/H/0192/005	PA 1635/1/4	WARNER CHILCOTT UK LIMITED	IE
Actonel Combi 35 mg + 500 mg film-coated tablets	SE/H/0192/004	PA 1635/2/1	WARNER CHILCOTT UK LIMITED	IE
Actonel Once a Week 35 mg film-coated tablets	SE/H/0192/003	PA 1635/1/3	WARNER CHILCOTT UK LIMITED	IE
Actonel Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 IU effervescent granules	SE/H/732/001/MR	PA 1635/3/1	WARNER CHILCOTT UK LIMITED	IE
Optinate 75 mg film-coated tablets	SE/H/0194/005	PA 1635/4/2	WARNER CHILCOTT UK LIMITED	IE
Optinate 75mg film-coated tablets	SE/H/0194/005	PA 1635/4/2	WARNER CHILCOTT UK LIMITED	IE
Optinate Once a Week 35 mg film-coated tablets	SE/H/0192/003	PA 1635/4/1	WARNER CHILCOTT UK LIMITED	IE
Optinate Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 IU effervescent granules	SE/H/0959/001/MR	PA 1635/5/1	WARNER CHILCOTT UK LIMITED	IE
Fortipan 5 mg filmdragerad tablett	SE/H/0193/001	15290	WARNER CHILCOTT UK LIMITED	SE
Fortipan 75 mg filmdragerad tablett	SE/H/0193/005	24566	WARNER CHILCOTT UK LIMITED	SE
Fortipan Septimum 35 mg filmdragerad tablett	SE/H/0193/003	17858	WARNER CHILCOTT UK LIMITED	SE
Actonel 30 mg film-coated tablets	SE/H/192/002/MR	PL 10947/0005	WARNER CHILCOTT UK LIMITED	UK

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Actonel 5 mg film-coated tablets	SE/H/192/001/MR	PL 10947/0004	WARNER CHILCOTT UK LIMITED	UK
Actonel Combi 35 mg + 1000 mg /880 IU film-coated tablets + effervescent granules	SE/H/732/001/MR	PL 10947/0007	WARNER CHILCOTT UK LIMITED	UK
Actonel Once a Week 35 mg film-coated tablets	SE/H/192/003/MR	PL 10947/0006	WARNER CHILCOTT UK LIMITED	UK