2 September 2021
EMA/PRAC/468922/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): alendronate

Procedure No.: PSUSA/00000078/202101

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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
GENALEN 70 mg compresse.	IT/H/0328/001	034172078	NEOPHARMED GENTILI SPA	IT
GENALEN 70 mg compresse.	IT/H/0328/001	034172066	NEOPHARMED GENTILI SPA	IT
GENALEN 70 mg compresse.	IT/H/0328/001	034172054	NEOPHARMED GENTILI SPA	IT
GENALEN 70 mg compresse.	IT/H/0328/001	034172041	NEOPHARMED GENTILI SPA	IT
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337878	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bonasol Once Weekly 70 mg Oral Solution	IE/H/0213/001	PA 1572/001/001	XEOLAS	IE
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337902	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337910	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
BONASOL eenmaal per week 70 mg drank	IE/H/0213/001	RVG 105077	CURAPHAR B.V.	NL
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622019	BRUNO FARMACEUTICI	IT
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622021	BRUNO FARMACEUTICI	IT
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622033	BRUNO FARMACEUTICI	IT
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622045	BRUNO FARMACEUTICI	IT
Soludronate Semanal 70 mg solución oral	IE/H/0213/001	73232	LABORATORIOS RUBIÓ, S.A.	ES
Alendronic Acid 70 mg Oral Solution	IE/H/0213/001	PL 34111/0001	XEOLAS	XI
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 726 9 8	LABORATOIRE XO	FR
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 0 4	LABORATOIRE XO	FR
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 1 1	LABORATOIRE XO	FR

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BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 2 8	LABORATOIRE XO	FR
Binosto 70 mg compresse effervescenti	DE/H/5609/001	040246011	ABIOGEN PHARMA S.P.A.	IT
Binosto 70 mg compresse effervescenti	DE/H/5609/001	040246023	ABIOGEN PHARMA S.P.A.	IT
Binosto 70 mg compresse effervescenti	DE/H/5609/001	040246035	ABIOGEN PHARMA S.P.A.	IT
Binosto 70 mg comprimidos efervescentes	DE/H/5609/001	5441654	LABORATÓRIOS ATRAL, S.A.	PT
Binosto 70 mg comprimidos efervescentes	DE/H/5609/001	5441662	LABORATÓRIOS ATRAL, S.A.	PT
Binosto 70 mg comprimidos efervescentes	DE/H/5609/001	5441670	LABORATÓRIOS ATRAL, S.A.	PT
STEOVESS 70 mg, comprimé effervescent	DE/H/5609/001	34009 266 831 1 5	LABORATOIRES EXPANSCIENCE	FR
STEOVESS 70 mg, comprimé effervescent	DE/H/5609/001	34009 266 832 8 3	LABORATOIRES EXPANSCIENCE	FR
STEOVESS 70 mg, comprimé effervescent	DE/H/5609/001	34009 583 493 9 3	LABORATOIRES EXPANSCIENCE	FR
Binosto 70 mg comprimate efervescente	DE/H/5609/001	4563/2012/02	GALENICA SA	RO
Binosto Once Weekly 70 mg effervescent tablets	DE/H/5609/001	PA0126/280/001	CLONMEL HEALTHCARE LTD.	IE
Binosto 70 mg comprimate efervescente	DE/H/5609/001	4563/2012/01	GALENICA SA	RO
Binosto 70 mg comprimate efervescente	DE/H/5609/001	4563/2012/03	GALENICA SA	RO
Binosto 70 mg αναβράζοντα δισκία	DE/H/5609/001	10117/16/14-05-2018	GALENICA SA	GR
Binosto, brusetabletter	DE/H/5609/001/E/001	62008	PHARMAPRIM AB	DK
Binosto 70 mg brusetabletter	DE/H/5609/001/E/001	18-12601	PHARMAPRIM AB	NO
Binosto 70 mg Brausetabletten	DE/H/5609/001/DC	83115.00.00	RECORDATI PHARMA GMBH	DE
Binosto 70 mg brustabletter	DE/H/5609/001	58621	PHARMAPRIM AB	SE

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
Binosto 70 mg poretabletit	DE/H/5609/001	36642	PHARMAPRIM AB	FI
Binosto 70 mg Brustabletter	DE/H/5609/001	36642	PHARMAPRIM AB	FI
Binosto 70 mg αναβράζοντα δισκία	DE/H/5609/001	023029	GALENICA SA	CY
Alendroninezuur Sandoz tablet 70 mg, filmomhulde tabletten	SE/H/0704/001	RVG 35326	SANDOZ B.V.	NL
ALENDROS 70 mg compresse	AT/H/0873/001	029051063	ABIOGEN PHARMA S.P.A.	IT
ALENDROS 70 mg compresse	AT/H/0873/001	029051075	ABIOGEN PHARMA S.P.A.	IT
ALENDROS 70 mg compresse	AT/H/0873/001	029051087	ABIOGEN PHARMA S.P.A.	IT
ALENDROS 70 mg compresse	AT/H/0873/001	029051099	ABIOGEN PHARMA S.P.A.	IT
FOSAMAX 70 mg comprimate	not available	5778/2013/01	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/03	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/04	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/02	MERCK SHARP & DOHME ROMANIA SRL	RO
ADRONAT 10 mg compresse	not available	029053030	NEOPHARMED GENTILI SPA	IT
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337878	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bonasol Once Weekly 70 mg Oral Solution	IE/H/0213/001	PA 1572/001/001	XEOLAS	IE
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337902	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bonasol 70 mg Solução Oral	IE/H/0213/001	5337910	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
BONASOL eenmaal per week 70 mg drank	IE/H/0213/001	RVG 105077	CURAPHAR B.V.	NL
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622019	BRUNO FARMACEUTICI	IT

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Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622021	BRUNO FARMACEUTICI	IT
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622033	BRUNO FARMACEUTICI	IT
Bonasol 70 mg soluzione orale settimanale	IE/H/0213/001	040622045	BRUNO FARMACEUTICI	IT
Alendronic Acid 70 mg Oral Solution	IE/H/0213/001	PL 34111/0001	XEOLAS	XI
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 726 9 8	LABORATOIRE XO	FR
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 0 4	LABORATOIRE XO	FR
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 1 1	LABORATOIRE XO	FR
BONASOL 70 mg, solution buvable	IE/H/0213/001	34009 301 727 2 8	LABORATOIRE XO	FR
ALENDROS 10 mg compresse	not available	029051036	ABIOGEN PHARMA S.P.A.	IT
ACIDE ALENDRONIQUE TEVA SANTE 70 mg, comprimé	not available	NL35745	TEVA SANTÉ	FR
FOSAMAX Once Weekly 70 mg tablets	AT/H/0870/001	PA1286/8/1	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Fosamax 70 mg tabletter	AT/H/0870/001	00-9210	MERCK SHARP & DOHME BV	NO
FOSAMAX 70 mg compresse	AT/H/0870/001	029052091	MSD ITALIA S.R.L.	IT
FOSAMAX 70 mg compresse	AT/H/0870/001	029052089	MSD ITALIA S.R.L.	IT
FOSAMAX 70 mg, comprimidos	AT/H/0870/001	3613585	MERCK SHARP & DOHME, LDA.	PT
FOSAMAX 70 mg compresse	AT/H/0870/001	029052077	MSD ITALIA S.R.L.	IT
FOSAMAX 70 mg compresse	AT/H/0870/001	029052065	MSD ITALIA S.R.L.	IT
FOSAMAX 70 mg één tablet per week	AT/H/0870/001	RVG 26202	MERCK SHARP & DOHME BV	NL
FOSAMAX 70 mg, comprimidos	AT/H/0870/001	3613288	MERCK SHARP & DOHME, LDA.	PT
FOSAMAX 70 mg, comprimidos	AT/H/0870/001	3613387	MERCK SHARP & DOHME, LDA.	PT

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
FOSAMAX vikutafla 70 mg, töflur	AT/H/0870/001	IS/1/01/007/01	MERCK SHARP & DOHME BV	IS
Fosamax einmal wöchentlich 70 mg Tabletten	AT/H/0870/001	1-24092	MERCK SHARP & DOHME GES.M.B.H.	AT
FOSAMAX 70 mg, comprimidos	AT/H/0870/001	3613486	MERCK SHARP & DOHME, LDA.	PT
FOSAMAX Semanal 70 mg comprimidos	AT/H/0870/001	63.955	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
FOSAMAX 70 mg, comprimidos	AT/H/0870/001	3735487	MERCK SHARP & DOHME, LDA.	PT
Fosamax, tabletter	AT/H/0870/001	32089	MERCK SHARP & DOHME BV	DK
FOSAMAX 70 mg comprimate	not available	5778/2013/01	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/03	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/04	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX 70 mg comprimate	not available	5778/2013/02	MERCK SHARP & DOHME ROMANIA SRL	RO
FOSAMAX Once weekly «μία φορά την εβδομάδα » δισκία 70 mg	UK/H/423/001/II/020	56276/06/29-11-2007	VIANEX S.A.	GR
FOSAMAX 70 mg, comprimé	AT/H/0870/001	34009 359 562 0 0	MSD FRANCE	FR
FOSAMAX 70 mg, comprimé	AT/H/0870/001	34009 359 563 7 8	MSD FRANCE	FR
FOSAMAX 70 mg, comprimé	AT/H/0870/001	34009 359 564 3 9	MSD FRANCE	FR
FOSAMAX 70 mg, comprimé	AT/H/0870/001	34009 359 566 6 8	MSD FRANCE	FR
FOSAMAX 70 mg, comprimé	AT/H/0870/001	34009 359 567 2 9	MSD FRANCE	FR
FOSAMAX T 70 mg tablete	not available	HR-H-982508386	MERCK SHARP & DOHME D.O.O.	HR
GENALEN 10 mg compresse	not available	034172027	NEOPHARMED GENTILI SPA	IT
GENALEN 10 mg compresse	not available	034172015	NEOPHARMED GENTILI SPA	IT
Acide Alendronique Mylan 70 mg, comprimé	not available	NL 32171	MYLAN S.A.S	FR
ADRONAT 70 mg compresse.	UK/H/0424/001	029053081	NEOPHARMED GENTILI SPA	IT
ADRONAT 70 mg	UK/H/0424/001	029053079	NEOPHARMED GENTILI SPA	IT

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compresse.				
ADRONAT 70 mg compresse.	UK/H/0424/001	029053067	NEOPHARMED GENTILI SPA	IT
ADRONAT 70 mg compresse.	UK/H/0424/001	029053093	NEOPHARMED GENTILI SPA	IT