02 December 2021
EMA/756993/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: risedronate

Procedure no.: PSUSA/00002648/202103

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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
Acrel 5 mg comprimidos recubiertos con película	SE/H/0193/001	66.952	THERAMEX IRELAND LIMITED	ES
Acrel 75 mg comprimidos recubiertos con película	SE/H/0192/005	69.786	THERAMEX IRELAND LIMITED	ES
Acrel semanal 35 mg comprimidos recubiertos con película.	SE/H/0193/003	65.906	THERAMEX IRELAND LIMITED	ES
Actokit D, combinatieverpakking	SE/H/0732/001	RVG 34894	THERAMEX IRELAND LIMITED	NL
Actokit, combinatieverpakking, filmomhulde tabletten.	SE/H/0192/004	RVG 31634	THERAMEX IRELAND LIMITED	NL
Actonel 30 mg compresse rivestite con film	SE/H/0192/002	034568067	THERAMEX IRELAND LIMITED	IT
Actonel 30 mg compresse rivestite con film	SE/H/0192/002	034568079	THERAMEX IRELAND LIMITED	IT
Actonel 30 mg comprimés pelliculés	SE/H/0192/002	BE212247	THERAMEX IRELAND LIMITED	BE
Actonel 30 mg comprimidos recubiertos con película	SE/H/0192/002	63.207	THERAMEX IRELAND LIMITED	ES
Actonel 30 mg filmomhulde tabletten	SE/H/0192/002	RVG 24990	THERAMEX IRELAND LIMITED	NL
Actonel 30 mg Filmtabletten	SE/H/0192/002	BE212247	THERAMEX IRELAND LIMITED	BE
Actonel 30 mg, filmomhulde tabletten.	SE/H/0192/002	BE212247	THERAMEX IRELAND LIMITED	BE
Actonel 35 mg compresse gastroresistenti	SE/H/0192/007	034568182	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse gastroresistenti	SE/H/0192/007	034568194	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse gastroresistenti	SE/H/0192/007	034568206	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse gastroresistenti	SE/H/0192/007	034568218	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse gastroresistenti	SE/H/0192/007	034568220	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse	SE/H/0192/007	034568232	THERAMEX IRELAND	IT

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gastroresistenti			LIMITED	
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568081	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568093	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568105	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568117	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568129	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg compresse rivestite con film.	SE/H/0192/003	034568131	THERAMEX IRELAND LIMITED	IT
Actonel 35 mg comprimido gastrorresistente	SE/H/0192/007	SE/H/0192/007	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281085	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281184	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281283	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281382	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281481	THERAMEX IRELAND LIMITED	PT
ACTONEL 35 mg comprimidos revestidos por película	SE/H/0192/003	4281580	THERAMEX IRELAND LIMITED	PT
Actonel 35 mg filmom obložene tablete	not available	HR-H-350046678	ALVOGEN PHARMA TRADING EUROPE EOOD	HR
Actonel 35 mg filmtabletta	SE/H/0192/003	OGYI-T- 8738/01	THERAMEX IRELAND LIMITED	HU
Actonel 35 mg filmtabletta	SE/H/0192/003	OGYI-T- 8738/02	THERAMEX IRELAND LIMITED	HU
Actonel 35 mg hebdomadaire comprimés gastrorésistants	SE/H/0192/007	BE504151	THERAMEX IRELAND LIMITED	BE

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 35 mg hebdomadaire comprimés pelliculés	SE/H/0192/003	BE244535	THERAMEX IRELAND LIMITED	BE
Actonel 35 mg wekelijks maagsapresistente tabletten	SE/H/0192/007	BE504151	THERAMEX IRELAND LIMITED	BE
Actonel 35 mg Wekelijks, filmomhulde tabletten	SE/H/0192/003	BE244535	THERAMEX IRELAND LIMITED	BE
Actonel 35 mg Wöchentlich Filmtabletten	SE/H/0192/003	BE244535	THERAMEX IRELAND LIMITED	BE
ACTONEL 35 mg WÖCHENTLICH MAGENSAFTRESISTENTE TABLETTEN	SE/H/0192/007	BE504151	THERAMEX IRELAND LIMITED	BE
ACTONEL 5 mg compresse rivestite con film	SE/H/0192/001	034568016	THERAMEX IRELAND LIMITED	IT
ACTONEL 5 mg compresse rivestite con film	SE/H/0192/001	034568028	THERAMEX IRELAND LIMITED	IT
ACTONEL 5 mg compresse rivestite con film	SE/H/0192/001	034568030	THERAMEX IRELAND LIMITED	IT
ACTONEL 5 mg compresse rivestite con film	SE/H/0192/001	034568042	THERAMEX IRELAND LIMITED	IT
ACTONEL 5 mg compresse rivestite con film	SE/H/0192/001	034568055	THERAMEX IRELAND LIMITED	IT
Actonel 5 mg comprimés pelliculés	SE/H/0192/001	BE212231	THERAMEX IRELAND LIMITED	BE
Actonel 5 mg comprimés pelliculés	SE/H/0192/001	2000060021	THERAMEX IRELAND LIMITED	LU
Actonel 5 mg comprimidos recubiertos con película	SE/H/0192/001	63.208	THERAMEX IRELAND LIMITED	ES
Actonel 5 mg filmomhulde tabletten	SE/H/0192/001	BE212231	THERAMEX IRELAND LIMITED	BE
Actonel 5 mg filmomhulde tabletten	SE/H/0192/001	RVG 25801	THERAMEX IRELAND LIMITED	NL
Actonel 5 mg Filmtabletten	SE/H/0192/001	BE212231	THERAMEX IRELAND LIMITED	BE
Actonel 5 mg Filmtabletten	SE/H/0192/001	2000060021	THERAMEX IRELAND LIMITED	LU
Actonel 75 mg compresse rivestite con	SE/H/0192/005	034568143	THERAMEX IRELAND	IT

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film.			LIMITED	
Actonel 75 mg compresse rivestite con film.	SE/H/0192/005	034568156	THERAMEX IRELAND LIMITED	IT
Actonel 75 mg compresse rivestite con film.	SE/H/0192/005	034568168	THERAMEX IRELAND LIMITED	IT
Actonel 75 mg compresse rivestite con film.	SE/H/0192/005	034568170	THERAMEX IRELAND LIMITED	IT
Actonel 75 mg comprimate filmate	SE/H/0192/005	5122/2012/01	THERAMEX IRELAND LIMITED	RO
Actonel 75 mg comprimate filmate	SE/H/0192/005	5122/2012/02	THERAMEX IRELAND LIMITED	RO
Actonel 75 mg comprimate filmate	SE/H/0192/005	5122/2012/03	THERAMEX IRELAND LIMITED	RO
Actonel 75 mg comprimate filmate	SE/H/0192/005	5122/2012/04	THERAMEX IRELAND LIMITED	RO
Actonel 75 mg comprimidos recubiertos con película	SE/H/0192/005	69.696	THERAMEX IRELAND LIMITED	ES
Actonel 75 mg filmomhulde tabletten	SE/H/0192/005	BE315472	THERAMEX IRELAND LIMITED	BE
Actonel 75 mg filmsko obložene tablete	SE/H/0192/005	H/08/00115/001	ZENTIVA, K.S.	SI
Actonel 75 mg filmsko obložene tablete	SE/H/0192/005	H/08/00115/002	ZENTIVA, K.S.	SI
Actonel 75 mg filmsko obložene tablete	SE/H/0192/005	H/08/00115/003	ZENTIVA, K.S.	SI
Actonel 75 mg filmsko obložene tablete	SE/H/0192/005	H/08/00115/004	ZENTIVA, K.S.	SI
Actonel 75 mg Filmtabletten	SE/H/0192/005	BE315472	THERAMEX IRELAND LIMITED	BE
ACTONEL 75 mg, comprimé pelliculé	SE/H/0192/005	34009 384 568 9 9	THERAMEX IRELAND LIMITED	FR
ACTONEL 75 mg, comprimé pelliculé	SE/H/0192/005	34009 384 569 5 0	THERAMEX IRELAND LIMITED	FR
ACTONEL 75 mg, comprimé pelliculé	SE/H/0192/005	34009 384 570 3 2	THERAMEX IRELAND LIMITED	FR
ACTONEL 75 mg, comprimé pelliculé	SE/H/0192/005	34009 384 572 6 1	THERAMEX IRELAND LIMITED	FR

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ACTONEL 75 mg, comprimés pelliculés	SE/H/0192/005	BE315472	THERAMEX IRELAND LIMITED	BE
Actonel 75 mg, filmomhulde tabletten	SE/H/0192/005	RVG 34632	THERAMEX IRELAND LIMITED	NL
Actonel Combi 35mg + 500mg film-coated tablets	SE/H/0192/004	PA22668/001/001	THERAMEX IRELAND LIMITED	IE
Actonel Combi 35mg + 500mg film-coated tablets	SE/H/0192/004	PA22668/001/001	THERAMEX IRELAND LIMITED	IE
Actonel Combi D 35 mg + 1000 mg / 880 IE filmomhulde tabletten + bruisgranulaat	SE/H/0732/001	BE304683	THERAMEX IRELAND LIMITED	BE
Actonel Combi D 35 mg + 1000 mg/880 I.E. Filmtabletten + Brausegranulat	SE/H/0732/001	BE304683	THERAMEX IRELAND LIMITED	BE
Actonel Combi D 35 mg + 1000 mg/880 I.E. Filmtabletten + Brausegranulat	SE/H/0732/001	2008040038	THERAMEX IRELAND LIMITED	LU
Actonel Combi D 35 mg + 1000 mg/880 UI, comprimés pelliculés et granulés effervescents	SE/H/0732/001	BE304683	THERAMEX IRELAND LIMITED	BE
Actonel Combi D 35 mg + 1000 mg/880 UI, comprimés pelliculés et granulés effervescents	SE/H/0732/001	2008040038	THERAMEX IRELAND LIMITED	LU
Actonel Combi D 35 mg film-coated tablets + 1000mg /880 IU effervescent granules	SE/H/0732/001	PL 49876/0013	THERAMEX IRELAND LIMITED	XI
Actonel einmal wöchentlich 35 mg Filmtabletten	SE/H/0192/003	1-24817	THERAMEX IRELAND LIMITED	AT
Actonel GR 35 mg γαστροανθεκτικό δισκίο	SE/H/0192/007	88803/08-09-2020	INNOVIS PHARMA	GR
Actonel Plus Ca & D 35mg film-coated tablets + 1000mg/880 IU Effervescent Granules	SE/H/0732/001	PA22668/002/001	THERAMEX IRELAND LIMITED	IE
Actonel semanal 35 mg comprimidos gastrorresistentes	SE/H/0192/007	81940	THERAMEX IRELAND LIMITED	ES

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Actonel semanal 35 mg comprimidos recubiertos con película	SE/H/0192/003	65.167	THERAMEX IRELAND LIMITED	ES
Actonel Wekelijks 35 mg, filmomhulde tabletten	SE/H/0192/003	RVG 28338	THERAMEX IRELAND LIMITED	NL
Actonel Wekelijks MSR 35 mg, maagsapresistente tabletten	SE/H/0192/007	RVG 118208	THERAMEX IRELAND LIMITED	NL
ACTONEL® «2 συνεχόμενες ημέρες το μήνα» 75 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/005	20392	INNOVIS PHARMA	CY
ACTONEL® «2 συνεχόμενες ημέρες το μήνα» 75 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/005	73038/001-12-2014	INNOVIS PHARMA	GR
Actonel® 30 mg Filmtabletten	SE/H/0192/002	48671.01.00	THERAMEX IRELAND LIMITED	DE
ACTONEL® 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/002	68871/01-12-2014	INNOVIS PHARMA	GR
Actonel® 5 mg Filmtabletten	SE/H/0192/001	48671.00.00	THERAMEX IRELAND LIMITED	DE
Actonel® 75 mg Filmtabletten	SE/H/0192/005	67799.00.00	THERAMEX IRELAND LIMITED	DE
Actonel® einmal wöchentlich 35 mg Filmtabletten	SE/H/0192/003	55437.00.00	THERAMEX IRELAND LIMITED	DE
ACTONEL® OAW/«μία φορά την εβδομάδα» 35 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/003	19723	INNOVIS PHARMA	CY
ACTONEL® OAW/«μία φορά την εβδομάδα» 35 mg επικαλυμμένα με λεπτό υμένιο δισκία	SE/H/0192/003	81506/01-12-2014	INNOVIS PHARMA	GR
Avestra Septimum, 35 mg, Filmdragerad tablett	SE/H/0195/003	17859	THERAMEX IRELAND LIMITED	SE
Avestra, 5 mg, Filmdragerad tablett	SE/H/0195/001	15292	THERAMEX IRELAND LIMITED	SE
Avestra, 75 mg, Filmdragerad tablett	SE/H/0195/005	24568	THERAMEX IRELAND LIMITED	SE
Fortipan Septimum, 35 mg,	SE/H/0193/003	17858	THERAMEX IRELAND	SE

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Filmdragerad tablett			LIMITED	
Fortipan, 5 mg, Filmdragerad tablett	SE/H/0193/001	15290	THERAMEX IRELAND LIMITED	SE
Fortipan, 75 mg, Filmdragerad tablett	SE/H/0193/005	24566	THERAMEX IRELAND LIMITED	SE
Norsed Combi D, 35 mg + 1000 mg/880 IE, Filmdragerad tablett och brusgranulat	SE/H/0959/001	22394	THERAMEX IRELAND LIMITED	SE
Norsed Septimum, 35 mg, Filmdragerad tablett	SE/H/0194/003	17860	THERAMEX IRELAND LIMITED	SE
Norsed, 75 mg, Filmdragerad tablett	SE/H/0194/005	24567	THERAMEX IRELAND LIMITED	SE
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570085	THERAMEX IRELAND LIMITED	IT
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570097	THERAMEX IRELAND LIMITED	IT
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570109	THERAMEX IRELAND LIMITED	IT
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570135	THERAMEX IRELAND LIMITED	IT
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570111	THERAMEX IRELAND LIMITED	IT
Optinate 35 mg compresse rivestite con film.	SE/H/0195/003	034570123	THERAMEX IRELAND LIMITED	IT
OPTINATE 5 mg compresse rivestite con film	SE/H/0195/001	034570010	THERAMEX IRELAND LIMITED	IT
OPTINATE 5 mg compresse rivestite con film	SE/H/0195/001	034570022	THERAMEX IRELAND LIMITED	IT
OPTINATE 5 mg compresse rivestite con film	SE/H/0195/001	034570034	THERAMEX IRELAND LIMITED	IT
OPTINATE 5 mg compresse rivestite con film	SE/H/0195/001	034570046	THERAMEX IRELAND LIMITED	IT
OPTINATE 5 mg compresse rivestite con film	SE/H/0195/001	034570059	THERAMEX IRELAND LIMITED	IT

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OPTINATE 75 mg compresse rivestite con film	SE/H/0195/005	034570147	THERAMEX IRELAND LIMITED	IT
OPTINATE 75 mg compresse rivestite con film	SE/H/0195/005	034570150	THERAMEX IRELAND LIMITED	IT
OPTINATE 75 mg compresse rivestite con film	SE/H/0195/005	034570162	THERAMEX IRELAND LIMITED	IT
OPTINATE 75 mg compresse rivestite con film	SE/H/0195/005	034570174	THERAMEX IRELAND LIMITED	IT
Optinate Combi D, 35 + 1000 mg/880 IE Filmdragerad tablett och brusgranulat	SE/H/0192/005	22391	THERAMEX IRELAND LIMITED	SE
Optinate Combi, Filmdragerad tablett	SE/H/0193/004	19776	THERAMEX IRELAND LIMITED	SE
Optinate Plus Ca & D 35 mg film-coated tablets + 1000 mg/880 IU Effervescent Granules	SE/H/0959/001	PA22668/003/001	THERAMEX IRELAND LIMITED	IE
Optinate Septimum 35 mg enterotabletter.	SE/H/0192/007	53583	THERAMEX IRELAND LIMITED	SE
Optinate Septimum 35 mg filmdragerade tabletter.	SE/H/0192/003	17857	THERAMEX IRELAND LIMITED	SE
Optinate Septimum 35 mg filmdrasjerte tabletter	not available	01-13110	THERAMEX IRELAND LIMITED	NO
Optinate Septimum 35 mg kalvopäällysteiset tabletit	SE/H/0192/003	17654	THERAMEX IRELAND LIMITED	FI
Optinate, 30 mg, Filmdragerad tablett	SE/H/0192/002	15297	THERAMEX IRELAND LIMITED	SE
Optinate, 5 mg, Filmdragerad tablett	SE/H/0192/001	15296	THERAMEX IRELAND LIMITED	SE
Optinate, 75 mg, Filmdragerad tablett	SE/H/0192/005	24565	THERAMEX IRELAND LIMITED	SE
Risebone DUO MAX filmtabletta	not available	OGYI-T-22651/02	PHARMA PATENT KFT.	HU
Risebone DUO MAX filmtabletta	not available	OGYI-T-22651/03	PHARMA PATENT KFT.	HU
Risebone DUO MAX filmtabletta	not available	OGYI-T-22651/04	PHARMA PATENT KFT.	HU
Risebone DUO MAX filmtabletta	not available	OGYI-T-22651/05	PHARMA PATENT KFT.	HU

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Risedronate Sodium Accord 30 mg film-coated tablets	IE/H/0544/002	PA 2315/140/002	ACCORD HEALTHCARE IRELAND LIMITED	IE
Risedronate Sodium Accord 30 mg film-coated tablets.	IE/H/0544/002	PL 20075/1068	ACCORD HEALTHCARE LIMITED	XI
Risedronate Sodium Accord 5 mg film coated tablets	IE/H/0544/001	PA 2315/140/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
Risedronate Sodium Accord 5 mg film-coated tablets	IE/H/0544/001	PL 20075/1067	ACCORD HEALTHCARE LIMITED	XI
Risedronate Sodium Accord Once A Week 35 mg film-coated tablets.	IE/H/0544/005	PA 2315/140/003	ACCORD HEALTHCARE IRELAND LIMITED	IE
Risedronate Sodium Accord Once a Week 35 mg film-coated tablets.	IE/H/0544/003	PL 20075/1069	ACCORD HEALTHCARE LIMITED	XI
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835098	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835100	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835112	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835124	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835136	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedronato Aurobindo 35 mg compresse rivestite con film	NL/H/2263/003	040835148	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Risedron-HEXAL 75 mg Filmtabletten	NL/H/2054/001	82270.00.00	HEXAL AG	DE