



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2018
EMA/PRAC/581390/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products for maintenance

Active substance(s): calcitriol

Procedure No.: PSUSA/00000495/201801



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
Rocaltrol 0,25 mikrograma meke kapsule	not available	HR-H-630148256	ROCHE D.O.O.	HR
Rocaltrol 0,5 mikrograma meke kapsule	not available	HR-H-153851334	ROCHE D.O.O.	HR
Rocaltrol 0,25 Mikrogramm Weichkapseln	not available	0178/07019148	N.V. ROCHE S.A.	LU
Rocaltrol 0,50 Mikrogramm Weichkapseln	not available	0178/07019149	N.V. ROCHE S.A.	LU
Rocaltrol 0,50 microgrammes capsules molles	not available	0178/07019149	N.V. ROCHE S.A.	LU
Rocaltrol 0,25 microgrammes capsules molles	not available	0178/07019148	N.V. ROCHE S.A.	LU
Rocaltrol 0,25, capsules 0,25 microgram	not available	RVG 08285	ROCHE NEDERLAND B.V.	NL
Rocaltrol 0,5, capsules 0,5 microgram	not available	RVG 08286	ROCHE NEDERLAND B.V.	NL
Rocaltrol 0,25 microgramas cápsulas moles	not available	4210282	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rocaltrol 0,25 microgramas cápsulas moles	not available	4210183	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rocaltrol 0,25 µg mäkké kapsuly	not available	86/0539/92-S	ROCHE SLOVENSKO S.R.O.	SK
Rocaltrol 0.25 microgram Capsules	not available	PL 00031/0122	ROCHE PRODUCTS LTD	UK
Rocaltrol 0.5 microgram Capsules	not available	PL 00031/0123	ROCHE PRODUCTS LTD	UK

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Rocaltrol 0,25 microgramme, capsule molle	not available	3400932532797	ROCHE	FR
Rocaltrol 0,25 microgramme, capsule molle	not available	3400932644322	ROCHE	FR
Rocaltrol 0.25 mikrogram mjuka kapslar	not available	9496	ROCHE AB - SOLNA	SE
Rocaltrol 0,25 Mikrogramm - Kapseln	not available	16.767	ROCHE AUSTRIA GMBH	AT
Rocaltrol 0,5 Mikrogramm - Kapseln	not available	16.768	ROCHE AUSTRIA GMBH	AT
Рокалтрол 0,25 микрограма меки капсули	not available	20020925	ROCHE BULGARIA EOOD	BG
Rocaltrol 0,25 microgram zachte capsules	not available	BE240292	N.V. ROCHE S.A.	BE
Rocaltrol 0,25 Mikrogramm Weichkapseln	not available	BE 240292	N.V. ROCHE S.A.	BE
Rocaltrol 0,50 microgram zachte capsules	not available	BE240301	N.V. ROCHE S.A.	BE
Rocaltrol 0,50 Mikrogramm Weichkapseln	not available	BE 240301	N.V. ROCHE S.A.	BE
Rocaltrol 0,25 microgrammes capsules molles	not available	BE240292	N.V. ROCHE S.A.	BE
Rocaltrol 0,50 microgrammes capsules molles	not available	BE240301	N.V. ROCHE S.A.	BE

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Rocaltrol 0,25 mikrogrami mīkstās kapsulas	not available	96-0198	ROCHE LATVIJA SIA	LV
Rocaltrol 0,5 mikrogrami mīkstās kapsulas	not available	01-0336	ROCHE LATVIJA SIA	LV
Rocaltrol 0,50 mcg capsule molli	not available	024280024	ROCHE S.P.A.	IT
Rocaltrol 0,25 mcg capsule molli	not available	024280012	ROCHE S.P.A.	IT
Rocaltrol 0,5 mikrogramm lágy kapszula	not available	OGYI-T-1214/04	ROCHE (MAGYARORSZÁG) KFT	HU
Rocaltrol 0,25 mikrogramm lágy kapszula	not available	OGYI-T-1214/03	ROCHE (MAGYARORSZÁG) KFT	HU
Rocaltrol 0,5 mikrograma mehke kapsule	not available	H/93/01369/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Rocaltrol 0,25 mikrograma mehke kapsule	not available	H/93/01369/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
ROCALTROL 0,25 mikrogramu měkké tobolky	not available	86/539/92-A/C	ROCHE S. R. O.	CZ
ROCALTROL 0,50 mikrogramu měkké tobolky	not available	86/539/92-B/C	ROCHE S. R. O.	CZ
Calcijex 1 mcg/ml Soluzione iniettabile per uso endovenoso	not available	028819011	ABBVIE S.R.L.	IT
ROCALTROL, 0,25 mikrogrammi pehmekapslid	not available	053994	ROCHE EESTI OÜ	EE

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Rocaltrol 0,50 microgramos cápsulas blandas	not available	55.974	ROCHE FARMA, S.A.	ES
Rocaltrol 0,25 microgramos cápsulas blandas	not available	55.973	ROCHE FARMA, S.A.	ES
Rocaltrol 0,25 mikrogram kapsler, myke	not available	6572	ROCHE NORGE AS, NORWAY	NO
Silkis 3 mikrogram/g salva	NL/H/0154/001	13865	GALDERMA NORDIC AB	FI
Silkis 3 mikrog/g voide	NL/H/0154/001	13865	GALDERMA NORDIC AB	FI
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	34009 351 115 5 5	GALDERMA INTERNATIONAL	FR
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	34009 351 117 8 4	GALDERMA INTERNATIONAL	FR
Silkis 3 micrograms per g ointment	NL/H/0154/001	PA 590/21/1	GALDERMA (UK) LIMITED	IE
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	34009 351 116 1 6	GALDERMA INTERNATIONAL	FR
Silkis 3 mikrogram per g salve	NL/H/0154/001	01-8149	GALDERMA NORDIC AB	NO
SILKIS 3 microgram/g zalf	NL/H/0154/001	RVG 16330	GALDERMA BENELUX B.V.	NL
Silkis 3 micrograms per g ointment	NL/H/0154/001	PL 10590/0047	GALDERMA (UK) LIMITED	UK
Silkis 3 mikrogramy/g mast	NL/H/0154/001	46/082/03-C	GALDERMA INTERNATIONAL	CZ

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Silkis® 3 µg/g Salbe	NL/H/0154/001	45143.00.00	GALDERMA LABORATORIUM GMBH	DE
Silkis 3 microgramos/g pomada	NL/H/0154/001	64.527	LABORATORIOS GALDERMA SA	ES
Silkis® 3 microgrammi per grammo di unguento	NL/H/0154/001	035765027	GALDERMA ITALIA S.P.A.	IT
Silkis 3 microgramas por grama pomada	NL/H/0154/001	4781985	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Silkis® 3 microgrammi per grammo di unguento	NL/H/0154/001	035765041	GALDERMA ITALIA S.P.A.	IT
Silkis 3 microgramas por grama pomada	NL/H/0154/001	3914280	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Silkis 3 microgramas por grama pomada	NL/H/0154/001	3914181	LABORATORIOS GALDERMA SA – SUCURSAL EM PORTUGAL	PT
Silkis® 3 microgrammi per grammo di unguento	NL/H/0154/001	035765039	GALDERMA ITALIA S.P.A.	IT
Rocaltrol® 0,5 µg, Weichkapseln	not available	4272.01.00	ROCHE PHARMA AG	DE
Rocaltrol® 0,25 µg, Weichkapseln	not available	4272.00.00	ROCHE PHARMA AG	DE
ROCALTROL 0,25 micrograme capsule moi	not available	7690/2015/02	ROCHE ROMANIA SRL	RO
ROCALTROL 0,25 micrograme capsule moi	not available	7690/2015/01	ROCHE ROMANIA SRL	RO