



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 September 2021
EMA/294429/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): calcitriol

Procedure No.: PSUSA/00000495/202101

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An agency of the European Union



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Rocaltrol 0,25 mikrogram kapsler, myke	not available	6572	ATNAHS PHARMA NETHERLANDS B.V.	NO
Rocaltrol 0,25 mikrograma meke kapsule	not available	HR-H-630148256	ATNAHS PHARMA NETHERLANDS B.V.	HR
Rocaltrol 0,5 mikrograma meke kapsule	not available	HR-H-153851334	ATNAHS PHARMA NETHERLANDS B.V.	HR
Rocaltrol 0,25 mikrogram mjuka kapslar	not available	9496	ATNAHS PHARMA NETHERLANDS B.V.	SE
ROCALTROL 0,25 microgramme, capsule molle	not available	34009 325 327 9 7	ROCHE	FR
ROCALTROL 0,25 microgramme, capsule molle	not available	34009 326 443 2 2	ROCHE	FR
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 0,50 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
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	351 115 5 OU 34009 351 115 5 5	GALDERMA INTERNATIONAL	FR
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	351 117-8 OU 34009 351 117 8 4	GALDERMA INTERNATIONAL	FR
Silkis 3 micrograms per g ointment	NL/H/0154/001	PA22743/014/001	GALDERMA INTERNATIONAL	IE
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	351 116-1 OU 34009 351 116 1 6	GALDERMA INTERNATIONAL	FR

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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 mikrogramy/g mast	NL/H/0154/001	46/082/03-C	GALDERMA INTERNATIONAL	CZ
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 S.A. - 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 S.A. - SUCURSAL EM PORTUGAL	PT
Silkis 3 microgramas por grama pomada	NL/H/0154/001	3914181	LABORATORIOS GALDERMA S.A. - SUCURSAL EM PORTUGAL	PT
Silkis® 3 microgrammi per grammo di unguento	NL/H/0154/001	035765039	GALDERMA ITALIA S.P.A.	IT
ROCALTROL, 0,25 mikrogrammi pehmekapslid	not available	053994	ATNAHS PHARMA NETHERLANDS B.V.	EE
Rocaltrol 0,25 mikrograma mehke kapsule	not available	H/93/01369/001	ATNAHS PHARMA NETHERLANDS B.V.	SI
Rocaltrol 0,5 mikrograma mehke kapsule	not available	H/93/01369/002	ATNAHS PHARMA NETHERLANDS B.V.	SI
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

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Rocaltrol 0,5 Mikrogramm - Kapseln	not available	16.768	ATNAHS PHARMA NETHERLANDS B.V.	AT
Rocaltrol 0,25 Mikrogramm - Kapseln	not available	16.767	ATNAHS PHARMA NETHERLANDS B.V.	AT
Rocaltrol 0,25, capsules 0,25 microgram	not available	RVG 08285	ATNAHS PHARMA NETHERLANDS B.V.	NL
Rocaltrol 0,5, capsules 0,5 microgram	not available	RVG 08286	ATNAHS PHARMA NETHERLANDS B.V.	NL
Rocaltrol 0.25 microgram Capsules.	not available	PL 43252/0028	ATNAHS PHARMA UK LIMITED	XI
Rocaltrol 0.5 microgram Capsules.	not available	PL 43252/0029	ATNAHS PHARMA UK LIMITED	XI
Rocaltrol 0,25 microgram zachte capsules	not available	BE240292	N.V. ROCHE S.A.	BE
Rocaltrol 0,25 Mikrogramm Weichkapseln	not available	BE240292	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	BE240301	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
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

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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 mikrogramm lágy kapszula	not available	OGYI-T-1214/03	ATNAHS PHARMA NETHERLANDS B.V.	HU
Rocaltrol 0,5 mikrogramm lágy kapszula	not available	OGYI-T-1214/04	ATNAHS PHARMA NETHERLANDS B.V.	HU
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 microgram zachte capsules	not available	BE240292	N.V. ROCHE S.A.	BE
Rocaltrol 0,25 Mikrogramm Weichkapseln	not available	BE240292	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	BE240301	N.V. ROCHE S.A.	BE
Silkis 3 mikrogram/g salva	NL/H/0154/001	13865	GALDERMA NORDIC AB	FI
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 0,25 mikrogramu	not available	86/539/92-A/C	ROCHE S. R. O.	CZ

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mëkkë tobolky				
ROCALTROL 0,50 mikrogramu mëkkë tobolky	not available	86/539/92-B/C	ROCHE S. R. O.	CZ
Rocaltrol 0,50 microgrammes capsules molles	not available	0178/07019149	N.V. ROCHE S.A.	LU
ROCALTROL 0,25 microgramme, capsule molle	not available	34009 325 327 9 7	ROCHE	FR
ROCALTROL 0,25 microgramme, capsule molle	not available	34009 326 443 2 2	ROCHE	FR
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 0,25 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 0,5 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 0,25 microgrammes capsules molles	not available	0178/07019148	N.V. ROCHE S.A.	LU
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
Silkis 3 mikrog/g voidé	NL/H/0154/001	13865	GALDERMA NORDIC AB	FI
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	351 115 5 OU 34009 351 115 5 5	GALDERMA INTERNATIONAL	FR

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SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	351 117-8 OU 34009 351 117 8 4	GALDERMA INTERNATIONAL	FR
Silkis 3 micrograms per g ointment	NL/H/0154/001	PA22743/014/001	GALDERMA INTERNATIONAL	IE
SILKIS 3 microgrammes/g, pommade	NL/H/0154/001	351 116-1 OU 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 mikrogramy/g mast	NL/H/0154/001	46/082/03-C	GALDERMA INTERNATIONAL	CZ
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 S.A. - 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 S.A. - SUCURSAL EM PORTUGAL	PT
Silkis 3 microgramas por grama pomada	NL/H/0154/001	3914181	LABORATORIOS GALDERMA S.A. - SUCURSAL EM PORTUGAL	PT
Silkis® 3 microgrammi per grammo di unguento	NL/H/0154/001	035765039	GALDERMA ITALIA S.P.A.	IT
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

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Rocaltrol 0,25 mikrogram kapsler, myke	not available	6572	ATNAHS PHARMA NETHERLANDS B.V.	NO
Rocaltrol 0,25, capsules 0,25 microgram	not available	RVG 08285	ATNAHS PHARMA NETHERLANDS B.V.	NL
Rocaltrol 0,5, capsules 0,5 microgram	not available	RVG 08286	ATNAHS PHARMA NETHERLANDS B.V.	NL
Rocaltrol 0.25 microgram Capsules.	not available	PL 43252/0028	ATNAHS PHARMA UK LIMITED	XI
Rocaltrol 0.5 microgram Capsules.	not available	PL 43252/0029	ATNAHS PHARMA UK LIMITED	XI
Rocaltrol® 0,25 µg, Weichkapseln	not available	4272.00.00	ATNAHS PHARMA NETHERLANDS B.V.	DE
Rocaltrol® 0,5 µg, Weichkapseln	not available	4272.01.00	ATNAHS PHARMA NETHERLANDS B.V.	DE
Rocaltrol 0,5 Mikrogramm - Kapseln	not available	16.768	ATNAHS PHARMA NETHERLANDS B.V.	AT
Rocaltrol 0,25 Mikrogramm - Kapseln	not available	16.767	ATNAHS PHARMA NETHERLANDS B.V.	AT
Rocaltrol 0,25 mikrograma meke kapsule	not available	HR-H-630148256	ATNAHS PHARMA NETHERLANDS B.V.	HR
Rocaltrol 0,5 mikrograma meke kapsule	not available	HR-H-153851334	ATNAHS PHARMA NETHERLANDS B.V.	HR
Rocaltrol 0,25 mikrogram mjuka kapslar	not available	9496	ATNAHS PHARMA NETHERLANDS B.V.	SE
Rocaltrol 0,25 mikrogrami mīkstās kapsulas	not available	96-0198	ATNAHS PHARMA NETHERLANDS B.V.	LV
Rocaltrol 0,5 mikrogrami mīkstās kapsulas	not available	01-0336	ATNAHS PHARMA NETHERLANDS B.V.	LV

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Rocaltrol 0,25 mikrogramm lágy kapszula	not available	OGYI-T-1214/03	ATNAHS PHARMA NETHERLANDS B.V.	HU
Rocaltrol 0,5 mikrogramm lágy kapszula	not available	OGYI-T-1214/04	ATNAHS PHARMA NETHERLANDS B.V.	HU
Rocaltrol 0,25 mikrograma mehke kapsule	not available	H/93/01369/001	ATNAHS PHARMA NETHERLANDS B.V.	SI
Rocaltrol 0,5 mikrograma mehke kapsule	not available	H/93/01369/002	ATNAHS PHARMA NETHERLANDS B.V.	SI
ROCALTROL, 0,25 mikrogrammi pehmekapslid	not available	053994	ATNAHS PHARMA NETHERLANDS B.V.	EE
Rocaltrol 0,25 mikrogrami mīkstās kapsulas	not available	96-0198	ATNAHS PHARMA NETHERLANDS B.V.	LV
Rocaltrol 0,5 mikrogrami mīkstās kapsulas	not available	01-0336	ATNAHS PHARMA NETHERLANDS B.V.	LV
Rocaltrol® 0,25 µg, Weichkapseln	not available	4272.00.00	ATNAHS PHARMA NETHERLANDS B.V.	DE
Rocaltrol® 0,5 µg, Weichkapseln	not available	4272.01.00	ATNAHS PHARMA NETHERLANDS B.V.	DE