



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/677233/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: calcitriol

Procedure no.: PSUSA/00000495/201501



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
Calcijex		028819011	Abbvie S.R.L.	IT
Calcijex		1-20488	Abbvie Gmbh	AT
Calcijex		219418	Abbvie, Lda.	PT
Difix		027231012	Promedica S.R.L.	IT
Difix		027231036	Promedica S.R.L.	IT
Rocaltrol		01-0336	Roche Latvija Sia	LV
Rocaltrol		024280012	Roche S.P.A.	IT
Rocaltrol		024280024	Roche S.P.A.	IT
Rocaltrol		053994	Roche Eesti Oü	EE
Rocaltrol		16.767	Roche Austria Gmbh	AT
Rocaltrol		16.768	Roche Austria Gmbh	AT
Rocaltrol		20020925	Roche Bulgaria Eood	BG
Rocaltrol		218 IS 212 F5	N.V. Roche S.A.	BE
Rocaltrol		218 IS 212 F5	N.V. Roche S.A.	LU
Rocaltrol		218 IS 213 F5	N.V. Roche S.A.	BE
Rocaltrol		218 IS 213 F5	N.V. Roche S.A.	LU
Rocaltrol		3400932532797	Roche	FR
Rocaltrol		3400932644322	Roche	FR
Rocaltrol		4210183	Roche Farmacêutica Química, Lda.	PT
Rocaltrol		4210282	Roche Farmacêutica Química, Lda.	PT
Rocaltrol		4272.00.00	Roche Pharma Ag	DE
Rocaltrol		4272.01.00	Roche Pharma Ag	DE
Rocaltrol		5363-I-721/10	Roche Farmaceutvska Družba D.O.O.	SI
Rocaltrol		5363-I-722/10	Roche Farmaceutvska Družba D.O.O.	SI
Rocaltrol		55.973	Andreu Roche, S.A.	ES
Rocaltrol		55.974	Andreu Roche, S.A.	ES
Rocaltrol		6572	F. Hoffmann-La Roche Ag	NO
Rocaltrol		7124/2006/01-02	Roche Romania Srl	RO
Rocaltrol		86/0539/92-S	Roche Slovensko S.R.O.	SK
Rocaltrol		86/539/92-A/C	Roche S.R.O.	CZ
Rocaltrol		86/539/92-B/C	Roche S.R.O.	CZ
Rocaltrol		9496	Roche 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
Rocaltrol		96-0198	Roche Latvija Sia	LV
Rocaltrol		OGYI-T-1214/ 04	Roche (Magyarország) Kft	HU
Rocaltrol		OGYI-T-1214/03	Roche (Magyarország) Kft	HU
Rocaltrol		PA 50/47/1	Roche Products Ltd	IE
Rocaltrol		PL 00031/0122	Roche Products Ltd	GB
Rocaltrol		PL 00031/0123	Roche Products Ltd	GB
Rocaltrol		RVG 08285	Roche Nederland B.V.	NL
Rocaltrol		RVG 08286	Roche Nederland B.V.	NL
Rocaltrol		UP/I-530-09/10-02/290	Roche D.O.O.	HR
Rocaltrol		UP/I-530-09/10-02/291	Roche D.O.O.	HR
Silkis	NL/H/0154/001	13865	Galderma Nordic Ab	FI
Silkis	NL/H/0154/001	351 115 5 OU 34009 351 115 5 5	Galderma International	FR
Silkis	NL/H/0154/001	351 116-1 OU 34009 351 116 1 6	Galderma International	FR
Silkis	NL/H/0154/001	351 117-8 OU 34009 351 117 8 4	Galderma International	FR
Silkis	NL/H/0154/001	45143.00.00	Galderma Laboratorium Gmbh	DE
Silkis	NL/H/0154/001	RVG 16330	Galderma Benelux B.V.	NL
Silkis	NL/H/0154/001/E01	01-8149	Galderma Nordic Ab	NO
Silkis	NL/H/0154/001/E01	035765027/M	Galderma Italia S.P.A.	IT
Silkis	NL/H/0154/001/E01	035765039/M	Galderma Italia S.P.A.	IT
Silkis	NL/H/0154/001/E01	035765039/M	Galderma Italia S.P.A.	IT
Silkis	NL/H/0154/001/E01	3914181	Laboratorios Galderma Sa – Sucursal Em Portugal	PT
Silkis	NL/H/0154/001/E01	3914280	Laboratorios Galderma Sa – Sucursal Em Portugal	PT
Silkis	NL/H/0154/001/E01	4781985	Laboratorios Galderma Sa – Sucursal Em Portugal	PT
Silkis	NL/H/0154/001/E01	64.527	Laboratorios Galderma, S.A.	ES
Silkis	NL/H/0154/001/E01	PL 10590/0047	Galderma (Uk) Limited	GB
Silkis	NL/H/0154/001/E02	46/082/03-C	Galderma International	CZ
Silkis	NL/H/0154/001/E02	PA 590/21/1	Galderma (Uk) Limited	IE