



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2023
EMA/27758/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: calcifediol

Procedure no.: PSUSA/00000491/202206

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



© European Medicines Agency, 2023. Reproduction is authorised provided the source is acknowledged.

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
Dedrogyl® 0,15 mg/ml, Tropfen zum Einnehmen, Lösung	not available	2050.00.00	DESMA GMBH	DE
Dédrogyl 0,15mg/ml, solution buvable en gouttes	not available	BE111124	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	BE
DEDROGYL 15 mg/100 ml, solution buvable en gouttes	not available	3178632	DESMA PHARMA	FR
Hidroferol 0,266 mg cápsulas blandas	not available	80.095	FAES FARMA, S.A.	ES
Dedrogyl 0,15 mg/ml Solução oral	not available	8497602	DESMA LABORATORIO FARMACÉUTICO SL	PT
Royaldee 30 mikrogram depotkapsel, mjuk	DE/H/5590/001	59064	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	SE
Royaldee, 30 microgram prolonged-release capsule, soft	DE/H/5590/001	PL 50784/0005	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	XI
Royaldee, 30 Mikrogramm, Weichkapsel retardiert	DE/H/5590/001	2202115.00.00	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	DE
Royaldee 30 mikrogram depotkapsel, myk	DE/H/5590/001	19-12808	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	NO

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
Royaldee	DE/H/5590/001	62564	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	DK
Royaldee 30 microgram prolonged-release capsules, soft	DE/H/5590/001	PA22774/001/001	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	IE
Royaldee 30 microgram, zachte capsule met verlengde afgifte	DE/H/5590/001	RVG 124799	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	NL
Royaldee, 30 microgramas, cápsula mole de libertação prolongada	DE/H/5590/001	5802012	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	PT
Royaldee 30 microgrammi capsula molle a rilascio prolungato	DE/H/5590/001	047870011	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	IT
Royaldee 30 microgramos cápsulas blandas de liberación prolongada	DE/H/5590/001	85519	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	ES
Royaldee 30 microgrammi capsula molle a rilascio prolungato	DE/H/5590/001	047870023	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	IT
Royaldee 30 microgrammi capsula molle a rilascio prolungato	DE/H/5590/001	047870035	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	IT

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
Rayaldee, 30 microgramas, cápsula mole de libertação prolongada	DE/H/5590/001	5823679	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	PT
Rayaldee, 30 microgramas, cápsula mole de libertação prolongada	DE/H/5590/001	5823661	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	PT
Hidroferol 0,266 mg solución oral	not available	53.683	FAES FARMA, S.A.	ES
Hidroferol 0,266 mg cápsulas blandas	not available	80.095	FAES FARMA, S.A.	ES
Hidroferol Choque 3 mg solución oral	not available	53.684	FAES FARMA, S.A.	ES
Hidroferol 0,1 mg/ml gotas orales en solución	not available	55.315	FAES FARMA, S.A.	ES
DIDROGYL, 0,15 mg/ ml, gocce orali, soluzione	not available	024139014	BRUNO FARMACEUTICI	IT
DIDROGYL, 0,15 mg/ ml, gocce orali, soluzione	not available	024139026	BRUNO FARMACEUTICI	IT