



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/PRAC/77562/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): calcifediol

Procedure No.: PSUSA/00000491/202106



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
DEDROGYL 15 mg/100ml solution buvable en gouttes	Not available	3400931786320	DESMA PHARMA SARL	FR
Dédrogyl 0,15mg/ml, solution buvable en gouttes	not available	BE111124	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	BE
Hidroferol 0,266 mg cápsulas blandas	not available	80.095	FAES FARMA, S.A.	ES
Hidroferol 0,266 mg solución oral	not available	53.683	FAES FARMA, S.A.	ES
Hidroferol Choque 3 mg solución oral	not available	53.684	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
Hidroferol 0,1 mg/ml gotas orales en solución	not available	55.315	FAES FARMA, S.A.	ES
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
Royaldee	DE/H/5590/001	62564	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	DK

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 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
Dedrogyl 0,15 mg/ml Solução oral	not available	8497602	DESMA LABORATORIO FARMACÉUTICOSL	PT