



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2018
EMA/261995/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Cefadroxil

Procedure no.: PSUSA/00000584/201707



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
Biodroxil 125 mg/5 ml - Pulver zur Herstellung einer Suspension zur Einnahme	not available	1-20818	SANDOZ GMBH	AT
Biodroxil 500 mg/5 ml-Pulver zur Herstellung einer Suspension zum Einnehmen	AT/H/0121/004	1-20821	SANDOZ GMBH	AT
Дурацеф 250 мг/5мл прах за перорална суспензия	not available	20030298	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
DURACEF 500 mg Tvrdé tobolky	not available	15/009/84-B/C	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	CZ
Cefadroxil HEXAL 500 mg Tabletten	DE/H/1475/001	60482.00.00	HEXAL AG	DE
Cefadroxil - 1 A Pharma 500 mg Tabletten	DE/H/1476/001	60575.00.00	1 A PHARMA GMBH	DE
GRÜNCEF® 1 g	not available	179.00.02	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Duracef 250 mg / 5 ml suukaudse suspensiooni pulber	not available	166497	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Duracef, 1 g lahustuvad tabletid	not available	152096	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Duracef 500 mg kõvakapslid	not available	166797	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
DURACEF® 250 mg / 5ml	not available	55731	JUSTE FARMA. S.L.U.	ES
DURACEF®	not available	55730	JUSTE FARMA. S.L.U.	ES
ORACEFAL 125 mg/5 ml, poudre pour suspension buvable	not available	320 188.0	BRISTOL-MYERS SQUIBB	FR

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ORACEFAL 250 mg/5 ml, poudre pour suspension buvable	not available	320 312-3	BRISTOL-MYERS SQUIBB	FR
ORACEFAL 500 mg/5 ml, poudre pour suspension buvable	not available	321 605-4	BRISTOL-MYERS SQUIBB	FR
ORACEFAL 500 mg, gélule	not available	3400932018390	BRISTOL-MYERS SQUIBB	FR
ORACEFAL 500 mg, gélule	not available	320 184-5	BRISTOL-MYERS SQUIBB	FR
ORACEFAL 500 mg, gélule	not available	320 182-2	BRISTOL-MYERS SQUIBB	FR
ORACEFAL 1 g, comprimé dispersible	not available	329 021-1	BRISTOL-MYERS SQUIBB	FR
Duracef 500 mg kietosios kapsulės	not available	LT/1/97/1240/002	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Duracef 250 mg/5 ml milteliai geriamajai suspensijai	not available	LT/1/97/1240/004	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Duracef 250 mg/5 ml milteliai geriamajai suspensijai	not available	LT/1/97/1240/005	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Duracef 1 g disperguojamosios tabletės	not available	LT/1/97/1240/003	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Duracef 500 mg cietās kapsulas	not available	98-0089	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
Duracef 250 mg/5 ml pulveris iekšļīgi lietojamas suspensijas pagatavošanai	not available	98-0863	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
DURACEF, 500 mg, kapsuļki	not available	R/0511	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL

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DURACEF, 250 mg/5 ml, proszek do sporządzania zawiesiny doustnej	not available	R/0508	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
DURACEF, 1 g, tabletki do sporządzania zawiesiny doustnej	not available	7646	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL