



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 September 2018
EMA/620546/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: 5 fluorouracil (topical application)

Procedure no.: PSUSA/00010000/201712



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
Efudix 5%, Zalf	not available	BE 054363	S.A. MEDA PHARMA N.V.	BE
Efudix 5%, Salbe	not available	BE 054363	S.A. MEDA PHARMA N.V.	BE
Efudix, 50 mg/g, cremă	not available	8082/2006/02	MEDA PHARMA GMBH & CO. KG	RO
Efudix 5%, Salbe	not available	2010/010691	S.A. MEDA PHARMA N.V.	LU
Efudix 5 POUR CENT, crème	not available	34009 321 842 6 2	MEDA PHARMA SAS	FR
Efudix 5 % Creme	not available	6029133.00.00	MEDA PHARMA GMBH & CO. KG	DE
Efudix 5 POUR CENT, crème	not available	34009 321 843 2 3	MEDA PHARMA SAS	FR
Efudix 5 POUR CENT, crème	not available	34009 376 872 4 9	MEDA PHARMA SAS	FR
Efudix, 50 mg/g, cremă	not available	8082/2006/01	MEDA PHARMA GMBH & CO. KG	RO
EFUDIX	not available	46/0245/71-C/S	MEDA PHARMA SPOL. S R.O.	SK
Efudix 50 mg/g kenőcs	not available	OGYI-T-841/01	MYLAN EPD KFT.	HU
Efudix 5% pommade	not available	BE 054363	S.A. MEDA PHARMA N.V.	BE
Efudix 5% pommade	not available	2010/010691	S.A. MEDA PHARMA N.V.	LU
Efudix 5% w/w Cream	not available	PA 1332/32/1	MEDA HEALTH SALES IRELAND LIMITED	IE

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
Efudix cream	not available	MA 806/01001	MEDA PHARMACEUTICALS LTD	MT
Ефудикс 50 mg/g крем	not available	20060388	MEDA PHARMA GMBH & CO. KG	BG
Efudix, 50 mg/g, krem	not available	R/3359	MEDA PHARMA GMBH & CO. KG	PL
Efudix, crème 50 mg/g	not available	RVG 06292	MEDA PHARMA B.V.	NL
Efudix 5% cream.	not available	PL 46302/0128	Mylan Products Limited	UK