



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 August 2023
EMA/380530/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): 5 fluorouracil (topical application)

Procedure No. PSUSA/00010000/202301



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
Efflurak 40 mg/g creme	SE/H/1820/001	5787551	PIERRE FABRE DERMO-COSMÉTIQUE PORTUGAL, LDA.	PT
Efflurak 40 mg/g creme	SE/H/1820/001	5787569	PIERRE FABRE DERMO-COSMÉTIQUE PORTUGAL, LDA.	PT
Efflurak 40 mg/g crème	SE/H/1820/001	BE550142	PIERRE FABRE BENELUX	BE
Efflurak 40 mg/g crème	SE/H/1820/001	BE550142	PIERRE FABRE BENELUX	BE
Efflurak 40 mg/g crème	SE/H/1820/001	BE550142	PIERRE FABRE BENELUX	BE
Efflurak 40 mg/g crème	SE/H/1820/001	BE550142	PIERRE FABRE BENELUX	BE
Efflurak 40 mg/g crème	SE/H/1820/001	0890337	PIERRE FABRE BENELUX	LU
Efflurak 40 mg/g crème	SE/H/1820/001	0890341	PIERRE FABRE BENELUX	LU
Efudix 5 % Creme	not available	6029133.00.00	VIATRIS HEALTHCARE GMBH	DE
EFUDIX 5 %, crème	not available	34009 321 842 6 2	MEDA PHARMA SAS	FR
EFUDIX 5 %, crème	not available	34009 321 843 2 3	MEDA PHARMA SAS	FR
EFUDIX 5 %, crème	not available	34009 376 872 4 9	MEDA PHARMA SAS	FR
Efudix 5% pommade	not available	BE 054363	MYLAN EPD BVBA/SPRL	BE
Efudix 5% pommade	not available	LU 2010010691	MYLAN EPD BVBA/SPRL	LU
Efudix 5% w/w Cream	not available	PA2010/049/001	MYLAN IRE HEALTHCARE LIMITED	IE
Efudix 5% w/w Cream.	not available	MA1507/00801	VIATRIS HEALTHCARE LTD	MT
EFUDIX 5%, Salbe	not available	BE 054363	MYLAN EPD BVBA/SPRL	BE
EFUDIX 5%, Salbe	not available	LU 2010010691	MYLAN EPD BVBA/SPRL	LU
Efudix 5%, Zalf	not available	BE 054363	MYLAN EPD BVBA/SPRL	BE
Efudix 50 mg/g kenőcs	not available	OGYI-T-841/01	MYLAN EPD KFT.	HU
EFUDIX 50 mg/g masť	not available	46/0245/71-CS	VIATRIS HEALTHCARE LTD	SK
Efudix, 50 mg/g, krem	not available	R/3359	MYLAN HEALTHCARE SP. Z.O.O.	PL
Efudix, crème 50 mg/g	not available	RVG 06292	MYLAN HEALTHCARE B.V.	NL
Tolak 40 mg/g cream	SE/H/1820/001	PL 00603/0247	PIERRE FABRE LIMITED	XI
Tolak 40 mg/g cream	SE/H/1820/001	PL 00603/0247	PIERRE FABRE LIMITED	XI
Tolak 40 mg/g crema	SE/H/1820/001	84849	PIERRE FABRE IBERICA,	ES

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			S.A.	
Tolak 40 mg/g crema	SE/H/1820/001	84849	PIERRE FABRE IBERICA, S.A.	ES
Tolak 40 mg/g Creme	SE/H/1820/001	139298	PIERRE FABRE MEDICAMENT	AT
Tolak 40 mg/g Creme	SE/H/1820/001	139298	PIERRE FABRE MEDICAMENT	AT
Tolak 40 mg/g Creme	SE/H/1820/001	2202036.00.00	PIERRE FABRE DERMO-KOSMETIK GMBH	DE
Tolak 40 mg/g Creme	SE/H/1820/001	2202036.00.00	PIERRE FABRE DERMO-KOSMETIK GMBH	DE
Tolak 40 mg/g crème	SE/H/1820/001	RVG 123084	PIERRE FABRE BENELUX	NL
Tolak 40 mg/g crème	SE/H/1820/001	RVG 123084	PIERRE FABRE BENELUX	NL
Tolak 40 mg/g kräm	SE/H/1820/001	57767	PIERRE FABRE MEDICAMENT	SE
Tolak 40 mg/g kräm	SE/H/1820/001	57767	PIERRE FABRE MEDICAMENT	SE
Tolak 40 mg/g krem	SE/H/1820/001	18-12224	PIERRE FABRE MEDICAMENT	NO
Tolak 40 mg/g krem	SE/H/1820/001	18-12224	PIERRE FABRE MEDICAMENT	NO
Tolak 40 mg/g krém	SE/H/1820/001	46/134/18-C	PIERRE FABRE MEDICAMENT	CZ
Tolak 40 mg/g krém	SE/H/1820/001	46/134/18-C	PIERRE FABRE MEDICAMENT	CZ
TOLAK 40 mg/g krém	SE/H/1820/001	46/0024/20-S	PIERRE FABRE MEDICAMENT	SK
TOLAK 40 mg/g krém	SE/H/1820/001	46/0024/20-S	PIERRE FABRE MEDICAMENT	SK
Tolak 40 mg/g κρέμα	SE/H/1820/001	132800/20/19-08-2021	PIERRE FABRE FARMAKA SA	GR
Tolak 40 mg/g κρέμα	SE/H/1820/001	132800/20/19-08-2021	PIERRE FABRE FARMAKA SA	GR
TOLAK 40 mg/g, crème	SE/H/1820/001	34009 301 932 6 6	PIERRE FABRE MEDICAMENT	FR
TOLAK 40 mg/g, crème	SE/H/1820/001	34009 301 932 7 3	PIERRE FABRE MEDICAMENT	FR
Tolak, 40 mg/g, krem	SE/H/1820/001	25952	PIERRE FABRE MEDICAMENT	PL
Tolak, 40 mg/g, krem	SE/H/1820/001	25952	PIERRE FABRE MEDICAMENT	PL
Tolak, creme	SE/H/1820/001	61069	PIERRE FABRE DERMATOLOGIE	DK
Tolak, creme	SE/H/1820/001	61069	PIERRE FABRE DERMATOLOGIE	DK
Tolerak 40 mg/g crema	SE/H/1820/001	046491015	PIERRE FABRE ITALIA S.P.A.	IT
Tolerak 40 mg/g crema	SE/H/1820/001	046491027	PIERRE FABRE ITALIA S.P.A.	IT
Tolerak 40 mg/g emulsiovoide	SE/H/1820/001	36052	PIERRE FABRE MEDICAMENT	FI
Tolerak 40 mg/g emulsiovoide	SE/H/1820/001	36052	PIERRE FABRE MEDICAMENT	FI