



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 September 2021
EMA/260271/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: betamethasone valerate / fusidic acid

Procedure no.: PSUSA/00000399/202101

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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
Fucibet Lipid 20 mg/g + 1 mg/g Crème	DK/H/2355/001	136727	LEO PHARMA A/S	AT
Fusidinsäure plus Betamethason Dermapharm 20 mg/g + 1 mg/g Crème	AT/H/0712/001/DC	138563	DERMAPHARM AG	AT
Fusicutan 20 mg/g + 1 mg/g Crème	AT/H/0600/001/DC	137085	DERMAPHARM GMBH	AT
Fucicort Lipid 20mg/g + 1mg/g crème	not available	BE413585	LEO PHARMA NV/SA	BE
Fucicort Lipid 20 mg/g + 1 mg/g crème	not available	BE413585	LEO PHARMA NV/SA	BE
FUCICORT LIPID 20 MG/G + 1 MG/G CREME	not available	BE413585	LEO PHARMA NV/SA	BE
FUCICORT 20 MG/ 1 MG/G Crème	not available	BE149755	LEO PHARMA NV/SA	BE
Fucicort 20mg/ 1mg/g Crème	not available	BE149755	LEO PHARMA NV/SA	BE
Fucicort 20 mg/ 1mg/g Crème	not available	BE149755	LEO PHARMA NV/SA	BE

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Фусибет Липид 20 mg/g + 1 mg/g крем	DK/H/2355/001	20150139	LEO PHARMA A/S	BG
Бетафузин 20 mg/g +1 mg/g крем	not available	20160187	ECOPHARM GROUP	BG
Фусикорт 20 mg/1 mg/g крем	not available	20000217	LEO PHARMA A/S	BG
Fusidic acid / Betamethasone Valerate Pharmascience International 20 mg/g + 1 mg/g Κρέμα	FR/H/0690/001/DC	022726	PHARMASCIENCE INTERNATIONAL LTD	CY
Fucicort® Cream	not available	8675	LEO PHARMA A/S	CY
Fucicort Lipid 20 mg/g + 1 mg/g krém	DK/H/2355/001	46/159/15-C	LEO PHARMA A/S	CZ
Fucicort 20 mg/g + 1 mg/g krém	not available	46/320/97-C	LEO PHARMA A/S	CZ
Fusidinsäure/Betamethason Mylan 20 mg/g + 1 mg/g Crème	IE/H/0631/001	90599.00.00	MYLAN GERMANY GMBH	DE
Fusidinsäure/Betamethason acis 20 mg/g+1 mg/g Creme	AT/H/0712/001	99060.00.00	ACIS ARZNEIMITTEL GMBH	DE

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Fusicutan plus Betamethason 20 mg/g + 1 mg/g Creme	AT/H/0600/001	94232.00.00	DERMAPHARM AG	DE
Fucicort® Lipid 20 mg/g + 1 mg/g Creme	not available	61359.00.00	LEO PHARMA GMBH	DE
Fucicort® 20 mg/g + 1mg/g Creme	not available	23792.00.00	LEO PHARMA GMBH	DE
Fusidinsyre/betamethasonvalerat "Leo"	DK/H/2355/001	53478	LEO PHARMA A/S	DK
Fusidinsyre/betamethasonvalerat "Mylan"	IE/H/0631/001	53215	MYLAN AB	DK
Fucicort	not available	12290	LEO PHARMA A/S	DK
Fucicort Lipid	not available	36901	LEO PHARMA A/S	DK
Fucicort, 20 mg/1 mg /g kreem	not available	084094	LEO PHARMA A/S	EE
Fucibet 20 mg/g + 1 mg/g crema	not available	60.797	LABORATORIOS LEO PHARMA, S.A.	ES

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Fusicutanbeta 20 mg/g + 1 mg/g crema	AT/H/0712/001/DC	83985	MIBE PHARMA ESPAÑA S.L.	ES
Fucicort 20 mg/g + 1 mg/g emulsiovoide	not available	9981	LEO PHARMA A/S	FI
DERMAFUSONE 20 mg/1 mg/g, crème	FR/H/0690/001	34009 301 569 3 3	LABORATOIRES BAILLEUL SA	FR
DERMAFUSONE 20 mg/1 mg/g, crème	FR/H/0690/001	34009 301 569 4 0	LABORATOIRES BAILLEUL SA	FR
DERMAFUSONE 20 mg/1 mg/g, crème	FR/H/0690/001	34009 301 569 5 7	LABORATOIRES BAILLEUL SA	FR
DERMAFUSONE 20 mg/1 mg/g, crème	FR/H/0690/001	34009 301 569 6 4	LABORATOIRES BAILLEUL SA	FR
Fusidic acid+Betamethasone valerate/Mylan 20 mg/g + 1 mg/g Κρέμα	IE/H/0631/001	72160/14-07-2020	MYLAN S.A.S	GR
Fucicort® Lipid 20 mg/g + 1 mg/g κρέμα	not available	4789/01-02-2013	LEO PHARMACEUTICAL HELLAS S.A.	GR
Fusicutan Plus 20 mg/g+1 mg/g krema	AT/H/0600/001/DC	HR-H-807587009	MIBE PHARMACEUTICALS D.O.O.	HR

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Fucicort krém	not available	OGYI-T-7542/01	LEO PHARMA A/S	HU
Eczibet 20mg/g + 1mg/g cream	IE/H/0631/001	PA0577/196/001	MCDERMOTT LABORATORIES LTD	IE
Fucibet® Lipid 20 mg/g + 1 mg/g cream	not available	PA 46/40/2	LEO LABORATORIES LIMITED	IE
Fucibet® 20 mg/g + 1 mg/g cream	not available	PA 46/40/1	LEO LABORATORIES LIMITED	IE
FUCIMIXBETA 20 mg/g + 1 mg/g crema	DK/H/2355/001	043295029	LEO PHARMA A/S	IT
FUCIMIXBETA 20 mg/g + 1 mg/g crema	DK/H/2355/001	043295017	LEO PHARMA A/S	IT
FUCIMIXBETA 20 mg/g + 1 mg/g crema	DK/H/2355/001	043295043	LEO PHARMA A/S	IT
FUCIMIXBETA 20 mg/g + 1 mg/g crema	DK/H/2355/001	043295031	LEO PHARMA A/S	IT
FUCICORT 20 mg/g + 1 mg/g Crema	not available	033402013	LEO PHARMA A/S	IT

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FUCICORT 20 mg/g + 1 mg/g Crema	not available	033402025	LEO PHARMA A/S	IT
Acido Fusidico e Betametasone Mylan 20 mg/g + 1 mg/g crema	IE/H/0631/001	042976011	MYLAN S.P.A.	IT
Acido Fusidico e Betametasone Mylan 20 mg/g + 1 mg/g crema	IE/H/0631/001	042976023	MYLAN S.P.A.	IT
Acido Fusidico e Betametasone Mylan 20 mg/g + 1 mg/g crema	IE/H/0631/001	042976035	MYLAN S.P.A.	IT
Acido Fusidico e Betametasone Mylan 20 mg/g + 1 mg/g crema	IE/H/0631/001	042976047	MYLAN S.P.A.	IT
Fusicutanbeta 20 mg/g + 1 mg/g crema	AT/H/0712/001	045358013	MIBE PHARMA ITALIA S.R.L.	IT
Fusicutanbeta 20 mg/g + 1 mg/g crema	AT/H/0712/001	045358025	MIBE PHARMA ITALIA S.R.L.	IT
Fusicutanbeta 20 mg/g + 1 mg/g crema	AT/H/0712/001	045358037	MIBE PHARMA ITALIA S.R.L.	IT
Fusicutanbeta 20 mg/g + 1 mg/g crema	AT/H/0712/001	045358049	MIBE PHARMA ITALIA S.R.L.	IT

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Fucicort 20 mg/1 mg/g kremas	not available	LT/1/94/1691/001	LEO PHARMA A/S	LT
Enosat 20 mg/1 mg/g kremas	LV/H/0191/001	LT/1/16/3963/001	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	LT
Enosat 20 mg/1 mg/g kremas	LV/H/0191/001	LT/1/16/3963/004	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	LT
Enosat 20 mg/1 mg/g kremas	LV/H/0191/001	LT/1/16/3963/003	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	LT
Enosat 20 mg/1 mg/g kremas	LV/H/0191/001	LT/1/16/3963/002	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	LT
Fucicort Lipid 20 mg/g + 1 mg/g crème	not available	2013110394	LEO PHARMA NV/SA	LU
Fucicort 20mg/ 1mg/g Crème	not available	2005068248	LEO PHARMA NV/SA	LU
Enosat 20 mg/1 mg/g krēms	LV/H/0191/001	16-0172	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	LV
Fucicort 20 mg/1 mg/g krēms	not available	96-0122	LEO PHARMA A/S	LV

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Fucibet® Cream, 20 mg/g + 1 mg/g	not available	MA1313/00201	LEO LABORATORIES LIMITED	MT
Fucibet Lipid, (20 mg + 1 mg)/g, krem	DK/H/2355/001	22452	LEO PHARMA A/S	PL
Fusicutan plus, (20 mg + 1 mg)/g, krem	AT/H/0600/001	23494	SUN-FARM SP. Z.O.O.	PL
Dermisil, (20 mg + 1 mg)/g, krem	LV/H/0191/001	23604	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Betametasona + Ácido fusídico Mylan 1 mg/g + 20 mg/g creme	IE/H/0631/001	5648571	MYLAN, LDA	PT
Betametasona + Ácido fusídico Mylan 1 mg/g + 20 mg/g creme	IE/H/0631/001	5648605	MYLAN, LDA	PT
Betametasona + Ácido fusídico Mylan 1 mg/g + 20 mg/g creme	IE/H/0631/001	5648613	MYLAN, LDA	PT
Fucicort 1 mg/g + 20mg/g, creme	not available	8685214	LEO PHARMA A/S	PT
Fucicort 1 mg/g + 20mg/g, creme	not available	8685206	LEO PHARMA A/S	PT

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Fucicort 1 mg/g + 20mg/g, creme	not available	5732763	LEO PHARMA A/S	PT
Fucicort 20mg/1mg pe gram, cremă	not available	1231/2008/01	LEO PHARMA A/S	RO
Fucicort 20mg/g+1mg/g dermálny krém	not available	46/0009/04-S	LEO PHARMA A/S	SK
Xemacort 20 mg/g + 1 mg/g cream	IE/H/0631/001	PL 04569/1625	GENERICS [UK] LIMITED	XI
Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream	FR/H/0690/001	PL 52607/0001 - 0001	TOPIQUAL	XI