



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2017
EMA/32524/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fusidic acid (systemic use)

Procedure no.: PSUSA/00010226/201605



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
Natrium Fusidat Essential Pharma 500 mg- Trockensubstanz zur Infusionsbereitung mit Lösungsmittel		1-19846	ESSENTIAL PHARMA	AT
Natrium Fusidat Essential Pharma 500 mg- Trockensubstanz zur Infusionsbereitung mit Lösungsmittel		1-19846	ESSENTIAL PHARMA	AT
Fucidin-Filmtabletten		13.998	LEO PHARMA GESELLSCHAFT M.B.H.	AT
Fucidin, pulver og solvens til koncentrat til infusionsvæske, opløsning		6611	LEO PHARMA A/S	DK
Fucidin, filmovertukne tabletter		3994	LEO PHARMA A/S	DK
Fucidin, oral suspension		4170	LEO PHARMA A/S	DK
Fucidine 250 mg comprimidos recubiertos con película		39.143	LABORATORIOS LEO PHARMA, S.A.	ES
Fucidin 250 mg filmdragerad tablett		9901	LEO PHARMA A/S	FI

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Fucidin 250 mg tabletti, kalvopäällysteinen		9901	LEO PHARMA A/S	FI
FUSIDATE DE SODIUM ESSENTIAL PHARMA 500 mg, poudre et solution pour usage parentéral à diluer		34009 556 661 1 0	ESSENTIAL PHARMA	FR
FUSIDATE DE SODIUM ESSENTIAL PHARMA 500 mg, poudre et solution pour usage parentéral à diluer		34009 556 661 1 0	ESSENTIAL PHARMA	FR
FUCIDINE 250 mg, comprimé pelliculé		34009 565 468 6 2	LABORATOIRES LEO	FR
FUCIDINE 250 mg, comprimé pelliculé		34009 565 881 0 7	LABORATOIRES LEO	FR
FUCIDINE 250 mg, comprimé pelliculé		34009 558 357 8 3	LABORATOIRES LEO	FR
FUCIDINE ENFANTS 250 mg/5 ml, suspension buvable en flacon.		34009 332 272 1 0	LABORATOIRES LEO	FR
FUCIDINE NOURRISSONS 100 mg/2 ml, suspension buvable en flacon		34009 332 271 5 9	LABORATOIRES LEO	FR

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
FUCIDINE 250 mg, comprimé pelliculé		34009 364 975 8 0	LABORATOIRES LEO	FR
FUCIDINE® 250 mg, comprimé pelliculés		34009 367 663 7 2	LABORATOIRES LEO	FR
FUCIDINE 250 mg, comprimé pelliculé		34009 332 192 8 4	LABORATOIRES LEO	FR
FUCIDIN® Δισκία		4393/12	LEO PHARMACEUTICAL HELLAS S.A.	GR
FUCIDIN®, Πόσιμο εναιώρημα		4787/22-01-2013	LEO PHARMACEUTICAL HELLAS S.A.	GR
Fucidin 250 mg tablets		PA 0046/004/014	LEO LABORATORIES LIMITED	IE
Fucidin 250 mg/5 ml Oral Suspension		PA 46/4/10	LEO LABORATORIES LIMITED	IE
DERMOMYCIN CAPSULE		021266046	AVANTGARDE S.P.A.	IT
Fucidin® Tablets		AA262/00503	PHAMA-COS LTD., PHARMA-COS HOUSE	MT

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Fucidin® 250 mg, filmomhulde tablet		RVG 01369	LEO PHARMA BV	NL
Fucidin 250 mg tableter, filmdrasjerte		7447	LEO PHARMA AS	NO
Fucidine 250 mg comprimido revestido		5351267	LEO PHARMA A/S	PT
Fucidine 250 mg comprimido revestido		5413786	LEO PHARMA A/S	PT
Fucidin 250 mg filmdragerade tableter		10965	LEO PHARMA AB	SE
Sodium Fusidate 500 mg for Intravenous Infusion		PL 41871/0001	ESSENTIAL PHARMA	UK
Sodium Fusidate 500 mg for Intravenous Infusion		PL 41871/0001	ESSENTIAL PHARMA	UK
Fucidin® Suspension		PL 00043/5014R	LEO LABORATORIES LTD	UK
Fucidin® Tablets		PL 00043/5000R	LEO LABORATORIES LTD	UK