30 November 2023
EMA/551959/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): rifamycin

Procedure No. PSUSA/00002641/202304

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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
RIFOCIN 250 mg/3 ml soluzione iniettabile per uso intramuscolare	not available	020009015	SANOFI S.R.L.	IT
RIFOCIN 500 mg/10 ml soluzione iniettabile per uso endovenoso	not available	020009054	SANOFI S.R.L.	IT
RIFOCIN 90 mg/18 ml concentrato e solvente per soluzione per uso intralesionale e uso cutaneo	not available	020009080	SANOFI S.R.L.	IT
RIFOCIN 250 mg/10 ml soluzione iniettabile per uso endovenoso	not available	020009041	SANOFI S.R.L.	IT
RIFAMYCINE CHIBRET 1 000 000 UI/100 g, pommade ophtalmique	not available	34009 309 154 6 2	LABORATOIRES THEA	FR
Rifocine I.V. 500 mg oplossing voor injectie	not available	BE069842	SANOFI BELGIUM	BE
RIFOCINE I.V. 500 mg Injektionslösung	not available	BE069842	SANOFI BELGIUM	BE
Rifocine I.V. 500 mg solution injectable	not available	BE069842	SANOFI BELGIUM	BE
OTOFA solution auriculaire, gouttes	not available	34009 328 052 0 4	BOUCHARA RECORDATI	FR
OTOFA solution auriculaire, gouttes	not available	0144448	BOUCHARA RECORDATI	LU
STADMYCIN 200 mg compresse a rilascio modificato	not available	046663011	EG S.P.A.	IT
STADMYCIN 200 mg compresse a rilascio modificato	not available	046663011	EG S.P.A.	IT
Rifocine I.V. 500 mg solution injectable	not available	0099857	SANOFI BELGIUM	LU

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
RIFAMYCINE CHIBRET 1000 000 UI POUR CENT, collyre en solution	not available	34009 309 152-3 3	LABORATOIRES THEA	FR
Relafalk 200 mg tabletter med modifisert frisetting	DE/H/5379/001	17-11946	DR. FALK PHARMA G.M.B.H.	NO
Relafalk 200mg tabletter med modificeret udløsning	DE/H/5379/001	60311	DR. FALK PHARMA G.M.B.H.	DK
Relafalk 200 mg modified-release tablets	DE/H/5379/001	PL 08637/0028	DR. FALK PHARMA G.M.B.H.	XI
Relafalk 200 mg módosított hatóanyagleadású tabletta	DE/H/5379/001	OGYI-T-23478/01	DR. FALK PHARMA G.M.B.H.	HU
Relafalk 200 mg tabletter med modifierad frisättning	DE/H/5379/001	57123	DR. FALK PHARMA G.M.B.H.	SE
Relafalk 200 mg säädellysti vapauttava tabletti	DE/H/5379/001	35622	DR. FALK PHARMA G.M.B.H.	FI
Relafalk, 200 mg, tabletki o zmodyfikowanym uwalnianiu	DE/H/5379/001	25180	DR. FALK PHARMA G.M.B.H.	PL
Релафалк 200 mg таблетки с изменено освобождаване	DE/H/5379/001	20190054	DR. FALK PHARMA G.M.B.H.	BG
Relafalk 200 mg δισκία ελεγχόμενης αποδέσμευσης	DE/H/5379/001	62907/16-5-2019	GALENICA SA	GR
Relafalk 200 mg comprimidos de liberación modificada	DE/H/5379/001	84120	DR. FALK PHARMA G.M.B.H.	ES
Relafalk 200 mg Tabletten mit veränderter Wirkstofffreisetzung	DE/H/5379/001	2200986.00.00	DR. FALK PHARMA G.M.B.H.	DE

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
Imfalda 200 mg comprimidos de libertação modificada	DE/H/5379/001	5764162	DR. FALK PHARMA G.M.B.H.	PT