



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2019
EMA/494737/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: roxithromycin

Procedure no.: PSUSA/00002669/201812

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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
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	196730505	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	196730506	SANOFI-AVENTIS AEBE	GR
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Surlid, filmovertrukne tabletter	not available	14923	SANOFI-AVENTIS DENMARK A/S	DK
Surlid, filmovertrukne tabletter	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
Surlid, filmovertrukne tabletter	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
Surlid, filmovertrukne tabletter	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
Surlid, filmovertrukne tabletter	not available	14923	SANOFI-AVENTIS DENMARK A/S	DK
RULID 150 MG, COMPRIME ENROBE	not available	329 038-1	SANOFI-AVENTIS FRANCE	FR
RULID 50 MG, COMPRIME SECABLE POUR SUSPENSION BUVABLE	not available	339 536-4	SANOFI-AVENTIS FRANCE	FR
RULID 50 MG, COMPRIME SECABLE POUR SUSPENSION BUVABLE	not available	343 732-9	SANOFI-AVENTIS FRANCE	FR
RULID	not available	196730504	SANOFI-AVENTIS AEBE	GR
RULID	not available	196730501 (1149/93)	SANOFI-AVENTIS AEBE	GR
RULID 150 MG, COMPRIME ENROBE	not available	337 613-1	SANOFI-AVENTIS FRANCE	FR
RULID	not available	196730502	SANOFI-AVENTIS AEBE	GR
RULID 150 MG, COMPRIME ENROBE	not available	337 612-5	SANOFI-AVENTIS FRANCE	FR
RULID	not available	196730503	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με	not available	18147	SANOFI-AVENTIS CYPRUS LTD	CY

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
λεπτό υμένιο δισκίο, 300 mg				
Rulide 300 mg comprimidos recubiertos con película	not available	61.363	SANOFI-AVENTIS, S.A.	ES
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	R/0859	SANOFI-AVENTIS FRANCE	PL
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID 300 MG	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid, 50 mg, tabletki do sporządzenia zawiesiny doustnej	not available	7859	SANOFI-AVENTIS FRANCE	PL
RULIDE 150 MG-FILMTABLETTEN	not available	1-18581	SANOFI-AVENTIS GMBH OSTERREICH	AT

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
Surlid 150 mg filmdragerade tabletter	not available	11136	SANOFI AB	SE
RULIDE 300 MG-FILMTABLETTEN	not available	1-20222	SANOFI-AVENTIS GMBH OSTERREICH	AT
RULID 150 MG	not available	20020149	SANOFI BULGARIA EOOD	BG
RULID 50 MG, COMPRIME PELLICULE	not available	34009 345 577 0 5	SANOFI-AVENTIS FRANCE	FR
RULID 50 MG, COMPRIME PELLICULE	not available	34009 330 734 8 0	SANOFI-AVENTIS FRANCE	FR
ASSORAL 150 mg compresse rivestite con film	not available	026919011	I.B.N. SAVIO S.R.L.	IT
ASSORAL 300 mg compresse rivestite con film.	not available	026919047	I.B.N. SAVIO S.R.L.	IT
OVERAL ADULTI 150 mg compresse rivestite con film	not available	026728016	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
OVERAL ADULTI 300 mg compresse rivestite con film	not available	026728055	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
OVERAL Bambini 50 mg compresse dispersibili	not available	026728030	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
ROXITHROMYCINE ZENTIVA 150 mg, comprimé pelliculé	not available	34009 378 132 8 0	ZENTIVA FRANCE	FR
ROXITHROMYCINE ZENTIVA 150 mg, comprimé pelliculé	not available	34009 361 669 3 6	ZENTIVA FRANCE	FR
ROXITHROMYCINE ZENTIVA 150 mg, comprimé pelliculé	not available	34009 378 131 1 2	ZENTIVA FRANCE	FR
RULID BAMBINI	not available	026727038	SANOFI S.P.A	IT
RULID 300	not available	026727040	SANOFI S.P.A	IT
RULID	not available	026727014	SANOFI S.P.A	IT

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
ROSSITROL	not available	026922017	SANOFI S.P.A	IT
ROSSITROL	not available	026922043	SANOFI S.P.A	IT
ROSSITROL	not available	026922031	SANOFI S.P.A	IT