



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 September 2022
EMA/654141/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): roxithromycin

Procedure No. PSUSA/00002669/202112



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
Rulide 150 mg Filmdabletten	not available	1-18581	SANOFI-AVENTIS GMBH OSTERREICH	AT
Rulide 300 mg Filmdabletten	not available	1-20222	SANOFI-AVENTIS GMBH OSTERREICH	AT
РУЛИД 150 mg, филмирани таблетки	not available	20020149	SANOFI-AVENTIS GROUPE	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
RULID 150 mg, comprimé enrobé	not available	329 038 1	SANOFI-AVENTIS FRANCE	FR
RULID 50 mg, comprimé séccable pour suspension buvable	not available	339 536-4	SANOFI-AVENTIS FRANCE	FR
RULID 50 mg, comprimé séccable pour suspension buvable	not available	343 732-9	SANOFI-AVENTIS FRANCE	FR
RULID 150 mg, comprimé enrobé	not available	337 613 1	SANOFI-AVENTIS FRANCE	FR
RULID 150 mg, comprimé enrobé	not available	337 612 5	SANOFI-AVENTIS FRANCE	FR
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
Roximin επικαλυμμένα με λεπτό υμένιο δισκία 150 mg/tab.	not available	105715/14/20-03-2015	GALENICA SA	GR
Roximin επικαλυμμένα με λεπτό υμένιο δισκία 300 mg/tab.	not available	105716/14/20-03-2015	GALENICA SA	GR
Rulid, επικαλυμμένο με	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR

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				
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR
Rulid, επικαλυμμένο με λεπτό υμένιο δισκίο, 300 mg	not available	1149/93/26-09-1994	SANOFI-AVENTIS AEBE	GR
Rulid 300 mg compresse rivestite con film	not available	026727040	SANOFI S.R.L.	IT
Rulid 150 mg compresse rivestite con film	not available	026727014	SANOFI 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
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
Rossitrol 150 mg compresse rivestite con film	not available	026922017	SANOFI S.R.L.	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 300 mg compresse rivestite con film	not available	026922043	SANOFI S.R.L.	IT
Rulid 150 mg coated tablets	not available	MA1359/03001	SANOFI S.R.L.	MT
RULID	not available	R/0859	SANOFI-AVENTIS FRANCE	PL
Rulid, 50 mg, tabletki do sporządzania zawiesiny doustnej	not available	7859	SANOFI-AVENTIS FRANCE	PL
Surlid 150 mg filmdragerade tabletter	not available	11136	SANOFI AB	SE