



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2017
EMA/695016/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: roxithromycin

Procedure no.: PSUSA/00002669/201612



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
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
ROSSITROL	not available	026922017	SANOFI SPA	IT
ROSSITROL	not available	026922043	SANOFI SPA	IT
ROSSITROL	not available	026922031	SANOFI SPA	IT
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
ROXITHROMYCINE ZENTIVA 150 MG, COMPRIME PELLICULE	not available	361 669-3	SANOFI-AVENTIS FRANCE	FR
ROXITHROMYCINE ZENTIVA 150 MG, COMPRIME PELLICULE	not available	378 131-1	SANOFI-AVENTIS FRANCE	FR
ROXITHROMYCINE ZENTIVA 150 MG, COMPRIME PELLICULE	not available	378 132-8	SANOFI-AVENTIS FRANCE	FR
RULID	not available	18147	SANOFI-AVENTIS CYPRUS LTD	CY
RULID	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULID	not available	196730501 (1149/93)	SANOFI-AVENTIS AEBE	GR

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RULID	not available	026727014	SANOFI SPA	IT
RULID	not available	082/02702	SANOFI MALTA LTD	MT
RULID	not available	R/0859	SANOFI-AVENTIS FRANCE	PL
RULID	not available	7859	SANOFI-AVENTIS FRANCE	PL
RULID 150 MG	not available	20020149	SANOFI BULGARIA EOOD	BG
RULID 150 MG, COMPRIME ENROBE	not available	329 038-1	SANOFI-AVENTIS FRANCE	FR
RULID 150 MG, COMPRIME ENROBE	not available	337 613-1	SANOFI-AVENTIS FRANCE	FR
RULID 150 MG, COMPRIME ENROBE	not available	337 612-5	SANOFI-AVENTIS FRANCE	FR
RULID 300	not available	026727040	SANOFI SPA	IT
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 50 MG, COMPRIME PELLICULE	not available	345 577-0	SANOFI-AVENTIS FRANCE	FR
RULID 50 MG, COMPRIME PELLICULE	not available	330 734-8	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 50 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	329 735-4	SANOFI-AVENTIS FRANCE	FR
RULID 50 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	345 578-7	SANOFI-AVENTIS FRANCE	FR
RULID BAMBINI	not available	026727038	SANOFI SPA	IT

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Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 150 mg, Filmtabletten	not available	14641.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 300 mg Filmtabletten	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 300 mg Filmtabletten	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 300 mg Filmtabletten	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Rulid® 300 mg Filmtabletten	not available	14641.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
RULIDE 150 MG-FILMTABLETTEN	not available	1-18581	SANOFI-AVENTIS GMBH OSTERREICH	AT
RULIDE 300 MG COMPRIMIDOS	not available	61363	SANOFI-AVENTIS, S.A.	ES
RULIDE 300 MG-FILMTABLETTEN	not available	1-20222	SANOFI-AVENTIS GMBH OSTERREICH	AT
SURLID	not available	14923	SANOFI-AVENTIS DENMARK A/S	DK

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SURLID	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
SURLID	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
SURLID	not available	13028	SANOFI-AVENTIS DENMARK A/S	DK
SURLID	not available	14923	SANOFI-AVENTIS DENMARK A/S	DK
SURLID	not available	11136	SANOFI AB	SE