



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/626672/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: roxithromycin

Procedure no.: PSUSA/00002669/201412



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
Overall		026728016	Istituto Luso Farmaco D'italia S.P.A.	IT
Overall		026728055	Istituto Luso Farmaco D'italia S.P.A.	IT
Overall Bambini		026728030	Istituto Luso Farmaco D'italia S.P.A.	IT
Rossitrol		026922017	Sanofi Spa	IT
Rossitrol		026922031	Sanofi Spa	IT
Rossitrol		026922043	Sanofi Spa	IT
Roxithromycin		47243.00.00	Axcount Generika GmbH Generika GmbH	DE
Roxithromycin		47243.01.00	Axcount Generika GmbH Generika GmbH	DE
Roxithromycin Ratiopharm		15/0129/01-S	Ratiopharm GmbH	SK
Roxithromycin Ratiopharm		15/0130/01-S	Ratiopharm GmbH	SK
Roxithromycine		361 669-3	Sanofi-Aventis France	FR
Roxithromycine		3616687	Sanofi-Aventis France	FR
Roxithromycine		3616701	Sanofi-Aventis France	FR
Roxithromycine		378 131-1	Sanofi-Aventis France	FR
Roxithromycine		378 132-8	Sanofi-Aventis France	FR
Sanofi		0006/09020186	Sanofi-Aventis Belgium	LU
Sanofi		0006/09020187	Sanofi Belgium	LU
Sanofi		0006/09020187	Sanofi-Aventis Belgium	LU

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Sanofi		026727014	Sanofi Spa	IT
Sanofi		026727038	Sanofi Spa	IT
Sanofi		026727040	Sanofi Spa	IT
Sanofi		082/02702	Sanofi Malta Ltd	MT
Sanofi		14641.00.00	Sanofi-Aventis Deutschland Gmbh	DE
Sanofi		14641.01.00	Sanofi-Aventis Deutschland Gmbh	DE
Sanofi		18147	Sanofi-Aventis Cyprus Ltd	CY
Sanofi		196730501 (1149/93)	Sanofi-Aventis Aebe	GR
Sanofi		20020149	Sanofi-Aventis Bulgaria Eood	BG
Sanofi		20020149	Sanofi-Aventis Bulgaria Eood	BG
Sanofi		329 038-1	Sanofi-Aventis France	FR
Sanofi		329 735-4	Sanofi-Aventis France	FR
Sanofi		330 734-8	Sanofi-Aventis France	FR
Sanofi		330 735-4	Sanofi-Aventis France	FR
Sanofi		337 612-5	Sanofi-Aventis France	FR
Sanofi		337 613-1	Sanofi-Aventis France	FR
Sanofi		339 536-4	Sanofi-Aventis France	FR
Sanofi		343 732-9	Sanofi-Aventis France	FR

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Sanofi		343 733-5	Sanofi-Aventis France	FR
Sanofi		345 577-0	Sanofi-Aventis France	FR
Sanofi		345 578-7	Sanofi-Aventis France	FR
Sanofi		7859	Sanofi-Aventis France	PL
Sanofi		BE238603	Sanofi Belgium	BE
Sanofi		BE238603	Sanofi-Aventis Belgium	BE
Sanofi		BE238612	Sanofi Belgium	BE
Sanofi		BE238612	Sanofi-Aventis Belgium	BE
Sanofi		R/0859	Sanofi-Aventis France	PL
Sanofie		1-18581	Sanofi-Aventis Gmbh Osterreich	AT
Sanofie		1-18581	Sanofi-Aventis Gmbh Osterreich	AT
Sanofie		1-20222	Sanofi-Aventis Gmbh Osterreich	AT
Sanofie		1-22231	Sanofi-Aventis Gmbh Osterreich	AT
Sanofie		1-22231	Sanofi-Aventis Gmbh Osterreich	AT
Sanofie		58506	Sanofi-Aventis Sa	ES
Sanofie		61363	Sanofi-Aventis Sa	ES
Surlid		10645	Sanofi Oy	FI
Surlid		11136	Sanofi Ab	SE

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Surlid		11136	Sanofi-Aventis Ab	SE
Surlid		13028	Sanofi-Aventis Denmark A/S	DK
Surlid		14923	Sanofi-Aventis Denmark A/S	DK