



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/80054/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: sulfametrole / trimethoprim, sulfadiazine / trimethoprim,
sulfamethoxazole / trimethoprim (co-trimoxazole)

Procedure no.: PSUSA/00010593/201903

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

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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
Bactrim (200 mg + 40 mg)/5 ml syrop	not available	R/3126	ROCHE POLSKA SP.O.O.	PL
Bactrim 160 mg + 800 mg compresse	not available	021978046	ROCHE S.P.A.	IT
Bactrim 40 mg/8 mg/ml sīrups	not available	96-0596	ROCHE LATVIJA SIA	LV
Bactrim 40 mg/ml + 8 mg/ml mikstur, suspensjon	not available	5668	ROCHE NORGE AS, NORWAY	NO
Bactrim 40 mg/ml + 8 mg/ml oral lösning	not available	8674	ROCHE AB - SOLNA	SE
Bactrim 400 mg/80 mg tableter	not available	5669	ROCHE NORGE AS, NORWAY	NO
Bactrim 400 mg/80 mg tableter	not available	8675	ROCHE AB - SOLNA	SE
Bactrim 80 mg/5 ml + 400 mg/5 ml sospensione orale	not available	021978061	ROCHE S.P.A.	IT
BACTRIM ADULTES, comprimé	not available	34009 300 106 9 3	ROCHE	FR
BACTRIM ADULTES, comprimé	not available	34009 554 434 8 3	ROCHE	FR
BACTRIM ADULTES, comprimé	not available	34009 550 643 1 2	ROCHE	FR
BACTRIM ADULTES, comprimé	not available	34009 300 106 9 3	ROCHE	FR
BACTRIM ADULTES, comprimé	not available	34009 554 434 8 3	ROCHE	FR
BACTRIM ADULTES, comprimé	not available	34009 550 643 1 2	ROCHE	FR
Bactrim forte 800 mg/160 mg tableter	not available	9259	ROCHE AB - SOLNA	SE
Bactrim forte 800/160 mg comprimés	not available	BE109304	N.V. ROCHE S.A.	BE

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
Bactrim forte 800/160 mg comprimés	not available	0178/07109487	N.V. ROCHE S.A.	LU
Bactrim forte 800/160 mg tabletten	not available	BE109304	N.V. ROCHE S.A.	BE
Bactrim forte 800/160 mg Tabletten	not available	BE109304	N.V. ROCHE S.A.	BE
Bactrim forte 800/160 mg Tabletten	not available	0178/07109487	N.V. ROCHE S.A.	LU
Bactrim FORTE, 800 mg + 160 mg, comprimido	not available	4689998	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Bactrim FORTE, 800 mg + 160 mg, comprimido	not available	9259267	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Bactrim FORTE, 800 mg + 160 mg, comprimido	not available	5701099	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Bactrim Forte, 800 mg + 160 mg, tabletki	not available	R/3127	ROCHE POLSKA SP.O.O.	PL
BACTRIM FORTE, comprimé	not available	34009 554 435 4 4	ROCHE	FR
BACTRIM FORTE, comprimé	not available	34009 321 970 4 0	ROCHE	FR
BACTRIM FORTE, comprimé	not available	34009 553 367 5 4	ROCHE	FR
BACTRIM FORTE, comprimé	not available	34009 554 435 4 4	ROCHE	FR
BACTRIM FORTE, comprimé	not available	34009 321 970 4 0	ROCHE	FR
BACTRIM FORTE, comprimé	not available	34009 553 367 5 4	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 057 2 0	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 059 5 9	ROCHE	FR

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
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 313 053 6 1	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 058 9 8	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 057 2 0	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 059 5 9	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 313 053 6 1	ROCHE	FR
BACTRIM NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 316 058 9 8	ROCHE	FR
Bactrim perfusione 400 mg/5 ml + 80 mg/5 ml concentrato per soluzione per infusione	not available	028313029	ROCHE S.P.A.	IT
Bactrim perfusione 400 mg/5 ml + 80 mg/5 ml concentrato per soluzione per infusione	not available	028313017	ROCHE S.P.A.	IT
Bactrim, 200 mg/5 ml + 40 mg/5 ml, xarope	not available	4690087	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Bactrim, 200 mg/5 ml + 40 mg/5 ml, xarope	not available	8259317	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Bactrim, 200 mg/5 ml + 40 mg/5 ml, xarope	not available	4690087	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
BACTRIM, 40 mg+8 mg/ml siirup	not available	052894	ROCHE EESTI OÜ	EE

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
Bactrim, 400 mg + 80 mg, tabletki	not available	R/2762	ROCHE POLSKA SP.O.O.	PL
BACTRIM, solution injectable pour perfusion	not available	34009 316 836 1 2	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 316 837 8 0	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 326 040 5 0	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 556 637 3 7	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 555 402 2 9	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 557 161 2 9	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 316 836 1 2	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 316 837 8 0	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 326 040 5 0	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 556 637 3 7	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 555 402 2 9	ROCHE	FR
BACTRIM, solution injectable pour perfusion	not available	34009 557 161 2 9	ROCHE	FR
Bactrimel, concentraat voor oplossing voor intraveneuze infusie 96 mg/ml	not available	RVG 07231	ROCHE NEDERLAND B.V.	NL
Bactrimel® (400+80) mg/5 ml amp, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	not available	73097/16/23.02.2017	ROCHE (HELLAS) SA	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
Bactrimel® (800+160) mg, δισκία	not available	51767/17/30-4-2019	ROCHE (HELLAS) SA	GR
Co-Trimoxazole 800 mg/160 mg Forte Tablets.	not available	PL 39699/0035	ASPEN PHARMA TRADING LIMITED	UK
Co-Trimoxazole 16 mg/80 mg per ml for Infusion.	not available	PL 39699/ 0044	ASPEN PHARMA TRADING LIMITED	UK
Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension	not available	PL 39699/ 0037	ASPEN PHARMA TRADING LIMITED	UK
Co-Trimoxazole 80 mg/400 mg Tablets.	not available	PL 39699/0036	ASPEN PHARMA TRADING LIMITED	UK
Co-Trimoxazole Tablets B.P. (400/80)	not available	PL 17736/0079	CHEMIDEX PHARMA LIMITED	UK
Eusaprim - Tabletten	not available	14.247	ASPEN PHARMA TRADING LIMITED	AT
Eusaprim 16 mg/ml+80 mg/ml, koncentrat till infusionsvätska, lösning	not available	9062	ASPEN PHARMA TRADING LIMITED	SE
EUSAPRIM 40 mg/200 mg/5 ml suspensie voor oraal gebruik	not available	BE058256	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 40 mg/200 mg/5 ml suspension buvable	not available	BE058256	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 40 mg/200 mg/5 ml suspension buvable	not available	2008019653	ASPEN PHARMA TRADING LIMITED	LU
EUSAPRIM 40 mg/200 mg/5 ml Suspension zum Einnehmen	not available	BE058256	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 40 mg/200 mg/5 ml Suspension zum	not available	2008019653	ASPEN PHARMA TRADING LIMITED	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
Einnehmen				
Eusaprim 8 mg/ml + 40 mg/ml mixtúra, dreifa	not available	691231	ASPEN PHARMA TRADING LIMITED	IS
Eusaprim 8 mg/ml + 40 mg/ml, oral suspension	not available	8677	ASPEN PHARMA TRADING LIMITED	SE
EUSAPRIM 80 mg/400 mg comprimés	not available	BE058222	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg comprimés	not available	2008019651	ASPEN PHARMA TRADING LIMITED	LU
EUSAPRIM 80 mg/400 mg tabletten	not available	BE058222	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg Tabletten	not available	BE058222	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg Tabletten	not available	BE058222	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg Tabletten	not available	2008019651	ASPEN PHARMA TRADING LIMITED	LU
EUSAPRIM 80 mg/400 mg/5 ml concentraat voor oplossing voor infusie	not available	BE096932	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	not available	BE096932	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM 80 mg/400 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung Cotrimoxazol (Sulfamethoxazol + Trimethoprim)	not available	2008019654	ASPEN PHARMA TRADING LIMITED	LU
EUSAPRIM 80 mg/400 mg/5 ml solution à diluer	not available	BE096932	ASPEN PHARMA TRADING LIMITED	BE

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pour perfusion				
EUSAPRIM 80 mg/400 mg/5 ml solution à diluer pour perfusion Co-trimoxazole (triméthoprime + sulfaméthoxazole)	not available	2008019654	ASPEN PHARMA TRADING LIMITED	LU
Eusaprim E® Suspension für Erwachsene 400 mg + 80 mg/5 ml Suspension zum Einnehmen	not available	6104219.00.00	ASPEN PHARMA TRADING LIMITED	DE
Eusaprim forte - Tabletten	not available	16.213	ASPEN PHARMA TRADING LIMITED	AT
EUSAPRIM Forte 160 mg/800 mg comprimés	not available	BE109295	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM Forte 160 mg/800 mg comprimés	not available	2008019652	ASPEN PHARMA TRADING LIMITED	LU
EUSAPRIM Forte 160 mg/800 mg tabletten	not available	BE109295	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM FORTE 160 mg/800 mg Tabletten	not available	BE109295	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM Forte 160 mg/800 mg Tabletten	not available	BE109295	ASPEN PHARMA TRADING LIMITED	BE
EUSAPRIM FORTE 160 mg/800 mg Tabletten	not available	2008019652	ASPEN PHARMA TRADING LIMITED	LU
Eusaprim forte 160 mg/800 mg tabletter	not available	9263	ASPEN PHARMA TRADING LIMITED	SE
Eusaprim Infusionszusatz-Ampullen	not available	16002	ASPEN PHARMA TRADING LIMITED	AT
Eusaprim K® Suspension für Kinder 200 mg + 40 mg/5 ml Suspension zum	not available	6104254.00.00	ASPEN PHARMA TRADING LIMITED	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
Einnehmen				
Eusaprim orale Suspension für Kinder	not available	14.631	ASPEN PHARMA TRADING LIMITED	AT
Eusaprim® forte Tabletten 800 mg + 160 mg	not available	6102143.00.00	ASPEN PHARMA TRADING LIMITED	DE
Lidaprim Forte 800 mg/160 mg apvalkotās tabletes	not available	94-0133	ROKITAN GMBH	LV
Lidaprim® Επικαλυμμένο με λεπτό υμένιο δισκίο	not available	79025/16/31-01-2017	ROKITAN GMBH	GR
SEPTRIN 80 mg/400 mg comprimidos.	not available	48.670	TEOFARMA S.R.L.	ES
Septrin 80 mg/400 mg per ampoule, concentrate for solution for infusion	not available	PA 1691/010/005	ASPEN PHARMA TRADING LIMITED	IE
Septrin 80 mg/400 mg Tablets	not available	PA 1691/010/001	ASPEN PHARMA TRADING LIMITED	IE
Septrin 80 mg/400 mg Tablets	not available	MA955/00504	ASPEN PHARMA TRADING LIMITED	MT
Septrin Adult 80 mg/400 mg per 5 ml Oral suspension	not available	PA 1691/010/004	ASPEN PHARMA TRADING LIMITED	IE
Septrin Forte 160 mg/800 mg Tablets	not available	PA 1691/010/002	ASPEN PHARMA TRADING LIMITED	IE
Septrin Forte 160 mg/800 mg Tablets	not available	MA955/00503	ASPEN PHARMA TRADING LIMITED	MT
Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension	not available	PA 1691/010/003	ASPEN PHARMA TRADING LIMITED	IE
Septrin Paediatric 40 mg/200 mg per 5 ml Oral Suspension	not available	MA955/00501	ASPEN PHARMA TRADING LIMITED	MT

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
Soltrim 160 mg/ 800 mg polvo y solución para solución inyectable	not available	54.920	ALMIRALL, S.A.	ES
TMS forte	not available	577.00.00	T&D PHARMA GMBH	DE
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 345 228 6 4	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 325 170 2 2	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 325 169 4 0	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 345 228 6 4	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 325 170 2 2	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA NOURRISSONS ET ENFANTS, suspension buvable	not available	34009 325 169 4 0	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA, comprimé	not available	34009 345 229 2 5	BOUCHARA RECORDATI	FR
TRIMADIAZ ANTRIMA, comprimé	not available	34009 345 229 2 5	BOUCHARA RECORDATI	FR