

21 February 2018 EMA/224020/2018 Procedure Management and Committees Support

# List of nationally authorised medicinal products

Active substance: Thiocolchicoside

Procedure no.: EMEA-H-N-PSR-J-0008



# ACARPIA SERVIÇOS FARMACEUTICOS LDA

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Moveril 4mg/2ml solution for injection, 6 ampoules 2 ml	Not Applicable	035861018	ACARPIA SERVIÇOS FARMACEUTICOS LDA	Italy	Not Applicable

### **LABORATOIRES ALTER**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Thiocolchicoside Alter 4 mg, comprimé	Not Applicable	NL 22344	Laboratoires ALTER	France	Not applicable

# ANGELINI FARMACÊUTICA, Lda

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Adalgur N	Not applicable	5663380, 5663281	Angelini Farmacêutica, Lda.	Portugal	Not applicable

#### **ARISTO PHARMA GmbH**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolchicoside	Not applicable	028746016	Aristo Pharma	Italy	Not applicable

### ARROW GÉNÉRIQUES

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Thiocolchicoside Arrow 4 mg, comprimé	Not applicable	NL 27343	Arrow Génériques	France	Not applicable

### **BIOGARAN**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Not applicable
Thiocolchicoside Biogaran 4 mg, comprimé	Not applicable	NL 27342	BIOGARAN	France	Not applicable
Thiocolchicoside Almus 4 mg, comprimé	Not applicable	NL 27974	BIOGARAN	France	Not applicable

### **CRISTERS**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Thiocolchicoside Cristers 4mg, comprimé	Not applicable	NL 27973	Cristers	France	Not applicable

### **DAIICHI SANKYO FRANCE**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Miorel 4 mg/2 ml, injectable solution (IM) in ampoule	Not applicable	NL 16704	Daiichi Sankyo France	France	Not applicable
Miorel 4 mg, capsule	Not applicable	NL 16703	Daiichi Sankyo France	France	Not applicable

### **DOC GENERICI S.r.I.**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolchicoside Doc Generici	Not applicable	034895	Doc Generici S.r.I.	Italy	Not applicable

# DOMPÉ FARMACEUTICI S.p.A.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Miotens 4 mg/2 ml soluzione iniettabile i.m.	Not applicable	034424010	Dompé farmaceutici S.p.A.	Italy	Not applicable

### **EG LABO – LABORATOIRES EUROGENERICS**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Thiocolchicoside EG 4 mg comprimé sécable	Not applicable	NL26739	EG labo	France	Not applicable

# EG S.p.A.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolchicoside EG 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035328018	EG SpA Italy	Italy	Not applicable

### **EPIFARMA S.r.I.**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Muscoflex	Not applicable	034914010	Epifarma S.r.l.	Italy	Not applicable

### GENERIS FARMACÊUTICA S.A.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolquicosido Generis 4 mg Comprimido	Not applicable	05/H/0304/001	Generis Farmacêutica S.A.	Portugal	Not applicable
Tiocolquicosido Arrowblue 4 mg Comprimido	Not applicable	05/H/0305/001	Generis Farmacêutica S.A.	Portugal	Not applicable

### I.B.N. Savio S.r.l.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tioside, 4mg/2ml soluzione iniettabile per uso intramuscolare	Not applicable	033982012	I.B.N. Savio S.r.I.	Italy	Not applicable
Tioside, 4 mg capsule rigide	Not applicable	033982024	I.B.N. Savio S.r.I	Italy	Not applicable

### KORANGI PRODUTOS FARMACÊUTICOS Lda

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Coltramyl 4 mg Comprimidos	Not applicable	2200996 5606272	Korangi Produtos Farmacêuticos Lda	Portugal	Not applicable
Coltramyl 4 mg/2 ml Solução	Not applicable	2201184 5615901	Korangi Produtos	Portugal	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
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injetável			Farmacêuticos		

### LABORATORIO FARMACEUTICO CT S.r.I.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Sciomir 2mg/ml injectable solution	Not applicable	034898027	Laboratorio Farmaceutico CT Srl	Italy	Not applicable

# MDM S.p.A.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Strialisin – 4 mg/2 ml soluzione iniettabile	Not applicable	035314	MDM S.p.A.	Italy	Not applicable

#### **MYLAN**

Specific Information for PASS107 Submissions

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolchicoside Mylan Generics 4 mg / 2 ml Injection (Solution in Ampoules)	Not applicable	035077015	Mylan SpA	Italy	Not applicable
Thiocolchicoside Mylan 4 mg, comprimé	Not applicable	NL 26056	Mylan SAS	France	Not applicable

### **SANDOZ SAS**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Thiocolchicoside Sandoz 4 mg, comprimé	Not applicable	NL 26704	Sandoz SAS	France	Not applicable

# SANDOZ S.p.A.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Tiocolchicoside sandoz	Not applicable	035758 010	Sandoz S.p.A	Italy	Not applicable

### **SANOFI-AVENTIS GROUPE**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Coltramyl 4 mg, comprimé	Not applicable	V 00533	Sanofi-aventis France	France	Not applicable
Coltramyl 4 mg/2 ml, solution for injection	Not applicable	V 00537	Sanofi-aventis France	France	Not applicable
Thiocolchicoside Zentiva 4mg, comprimé	Not applicable	NL 24233	Sanofi-aventis France	France	Not applicable
Muscoril cps	Not applicable	63/168/98-C,	sanofi-aventis, s.r.o. Czech Republic	Czech Republic	Not applicable
Muscoril inj.	Not applicable	63/167/98-C	sanofi-aventis, s.r.o. Czech Republic	Czech Republic	Not applicable
Musco-ril caps. 4mg/cap	Not applicable	45294/21-09- 2009	sanofi-aventis AEBE	Greece	Not applicable
Musco-ril inj.sol. 4mg/2ml amp	Not applicable	45292/21-09- 2009	sanofi-aventis AEBE	Greece	Not applicable
MuscoriL 4 mg capsule rigide	Not applicable	015896107	Sanofi S.p.A.	Italy	Not applicable
Muscoril 8 mg capsule rigide	Not applicable	015896119	Sanofi S.p.A.	Italy	Not applicable
Muscoril 8 mg compresse orodispersibili	Not applicable	015896121	Sanofi S.p.A.	Italy	Not applicable
Muscoril 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	015896018	Sanofi S.p.A.	Italy	Not applicable
Tiocolchicoside Zentiva 4 mg capsule rigide	Not applicable	033009034	Zentiva Italia S.r.l.	Italy	Not applicable
Tiocolchicoside	Not applicable	033009022	Zentiva Italia	Italy	Not

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Zentiva 4 mg/2ml soluzione iniettabile per uso intramuscolare			S.r.l.		applicable
MuscoriL 4 mg hard capsule	Not applicable	AA 082/09801	Sanofi Malta Ltd	Malta	Not applicable
Relmus Capsules 4 mg	Not applicable	(20) – 8181503 (30) – 5594452	Sanofi – Produtos Farmacêuticos, Lda.	Portugal	Not applicable
Relmus Capsules 8 mg	Not applicable	(10) - 5605837 (10) - 5605829 (14) - 5593108 (14) - 5593074	Sanofi – Produtos Farmacêuticos, Lda.	Portugal	Not applicable
Relmus Orodispersible tablet 8 mg	Not applicable	(10) – 5605845 (14) – 5593066	Sanofi – Produtos Farmacêuticos, Lda.	Portugal	Not applicable
Relmus Solution for injection 4 mg/2 ml	Not applicable	(6) – 8181602 (10) - 5605852	Sanofi – Produtos Farmacêuticos, Lda.	Portugal	Not applicable

### S.F. GROUP S.r.I.

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Legal Basis
Decontril 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035078017	S.F. Group S.r.l.	Italy	Not applicable
Teraside	Not applicable	035966011	S.F. Group S.r.l.	Italy	Not applicable

# SPA-Società Prodotti Antibiotici S.p.A.

Product Name (in authorisatio n country)	MRP/DCP Authorisatio n number	Authorisatio n Number of product in the member state	MAH of product in the member state	Member State where product is authorise d	Legal Basis	Customer Account Number (only for PASS107	Purchas e Order Number (only for PASS 107)
Miorexil 4 mg solution for injection for intramuscular	Not applicable	036320012	SPA- Società Prodotti Antibiotic i S.p.A.	Italy	Not applicabl e	603962	Not applicable

### **UNION HEALTH S.r.I.**

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	MEMBER STATE WHERE PRODUCT IS AUTHORISED	Legal Basis
Tiocolchicoside Union Health 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035073016	Union Health Srl	Italy	Not applicable

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Vascotasin 35 mg módosított hatóanyagleadású tabletta	EE/H/0134/001	OGYI-T-21590/01	Actavis Group PTC ehf.	Hungary
Vascotazin	EE/H/0134/001	17685	Actavis Group PTC ehf.	Poland
Vascotazin 35 mg	EE/H/0134/001	41/0587/10-S	Actavis Group PTC ehf.	Slovakia
Moduxin MR 35 mg Protevasc 35 mg Moduxin MR 35 mg	HU/H/0310/001/MR HU/H/0310/001/MR HU/H/0310/001/MR	20110539 83/686/11-C OGYI-T-20603/04 (180x); OGYI-T- 20603/03 (120x); OGYI-T-20603/02 (60x); OGYI-T- 20603/05 (30x)	Gedeon Richter Plc. Gedeon Richter Plc. Gedeon Richter Plc.	Bulgaria Czech Republic Hungary
Moduxin 35 mg Moduxin 35 mg	HU/H/0310/001/MR HU/H/0310/001/MR	11-0503 LT/1/11/2616/001 (60x); LT/1/11/2616/003 (180x); LT/1/11/2616/002 (120x)	Gedeon Richter Plc. Gedeon Richter Plc.	Latvia Lithuania
Protevasc SR 35 mg	HU/H/0310/001/MR	18820	Gedeon Richter Polska Sp. Z.o.o.	Poland
Moduxin MR 35 mg	HU/H/0310/001/MR	4234/2012/02 (120x); 4234/2012/01 (60x); 4234/2012/03 (180x); 4234/2012/04 (30x)	Gedeon Richter, Romania	Romania
MODUXIN 20 mg	national applicaton	4940/2004/01	Gedeon Richter, Romania	Romania
Protevasc 35 mg	HU/H/0310/001/MR	41/0438/11-S	Gedeon Richter Plc.	Slovak Republic
Trimetazidina Labesfal, 35mg Comprimidos de libertação	NA	5261946 5261953	Labesfal Genéricos S.A.	Portugal

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
prolongada Trimetazidina Labesfal 20mg Comprimidos revestidos	NA	4746798 4746897	Labesfal Genéricos S.A.	Portugal
TRIMETAZIDINA CINFA 20 mg comprimidos recubiertos con película EFG	Not applicable	68.228	Laboratorios Cinfa, S.A. Olaz-Chipi, 10 (Pol. Areta)31620 Huarte (Spain)	SPAIN
Trimetazidina Cinfa 20 mg Comprimidos revestidos por película	Not applicable	PVC/PE/PVDC-AL:  5359286 (20 units)  5359385 (60 units)  PVC-PVDC/ALU:  5359088 (20 units)  5359187(60 units)	Cinfa Portugal, Lda. Avda. Tomás Ribeiro, 43; Bloco 1-4B (Edif. Neopark) 2790- 221Carnaxide (Portugal)	PORTUGAL
Trimetazidina Generis 20 mg Comprimidos Revestidos	NA	4747481 4747580	Generis Farmacêutica, S.A.	Portugal
Trimetazidina Generis 35 mg Comprimido de libertação prolongada Revestidos	NA	5170261 5170279	Generis Farmacêutica, S.A.	Portugal
Lupamadazine 35mg Tablette mit veränderter Wirkstofffreisetzung	DE/H/2652/01/DC	80108.00.00	Lupin (Europe) Limited	Germany
Trimetazidina PharmaKern 35 mg	DE/H/2652/01/DC	5383872, 5383906, 5383914, 5383922	PharmaKERN Portugal	Portugal

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Comprimido de libertacao prolongada			Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, No 11, 30, SL 31. Miraflores 1495- 139 Algés	
Trimetazigen MR 35mg Таблетки с удължено освобождаване	DE/H/2653/001/DC	201110150/09.03.2011	Mylan S.A.S	Bulgaria
Trimetazidin Mylan 35mg tablety s prodlouženým uvolňováním	DE/H/2653/001/DC	83/199/11-C	Mylan S.A.S	Czech Republic
TRIMETAZIDINE MYLAN 20 mg, comprimé pelliculé	NA	NL 22978	Mylan S.A.S	France
TRIMETAZIDINE MYLAN 20 mg/ml, solution buvable en gouttes	NA	NL 23040	Mylan S.A.S	France
TRIMETAZIDINE MYLAN 35 mg, comprimé pelliculé à libération modifiée	NA	NL 38502	Mylan S.A.S	France
Lutrazine 35mg Retardtabletten	DE/H/2653/001/DC	80109.00.00	Mylan S.A.S	Germany
Trimetazidine Mylan 35mg retard	DE/H/2653/001/DC	OGYI-T-21717/01, OGYI-T-21717/02,	Mylan S.A.S	Hungary

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
tabletta		OGYI-T-21717/03, OGYI-T-21717/04, OGYI-T-21717/05, OGYI-T-21717/06, OGYI-T-21717/07, OGYI-T-21717/08		
Trimetazydyna Mylan	DE/H/2653/001/DC	18762	Mylan S.A.S	Poland
Trimetazidina Mylan 35mg Comprimido de libertação prolongada	DE/H/2653/001/DC	5383807, 5383773, 5383823, 5383815	Mylan Lda	Portugal
Trimetazidina Mylan (20 mg)	NA	4746988, 4747085	Mylan Lda	Portugal
Trimetazidina Mylan 35mg comprimate cu eliberare prelungită	DE/H/2653/001/DC	3418/2011/01, 3418/2011/02, 3418/2011/03, 3418/2011/04, 3418/2011/05, 3418/2011/06, 3418/2011/07, 3418/2011/09, 3418/2011/10, 3418/2011/10, 3418/2011/11, 3418/2011/11, 3418/2011/12, 3418/2011/14, 3418/2011/15, 3418/2011/16, 3418/2011/17, 3418/2011/18, 3418/2011/19, 3418/2011/19, 3418/2011/19,	Mylan S.A.S	Romania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
		3418/2011/21, 3418/2011/22, 3418/2011/23, 3418/2011/24		
Trimetazidin Mylan 35 mg	DE/H/2653/001/DC	41/0064/11-S	Mylan S.A.S	Slovakia
Energotrim 35 mg prolonged release tablet	HU/H/0347	20110185	SANDOZ PHARMACEUTICALS D.D.	Bulgaria
Trimetazidina Sandoz	National	5297056, 5297064	Sandoz Farmacêutica, Lda.	Portugal
Trimetazidine Sandoz 35 mg retard tabletta	HU/H/0347	OGYI-T-21756/24 OGYI-T-21756/23 OGYI-T-21756/22 OGYI-T-21756/21 OGYI-T-21756/20 OGYI-T-21756/19 OGYI-T-21756/19 OGYI-T-21756/17 OGYI-T-21756/16 OGYI-T-21756/15 OGYI-T-21756/14 OGYI-T-21756/13 OGYI-T-21756/12 OGYI-T-21756/10 OGYI-T-21756/10 OGYI-T-21756/09 OGYI-T-21756/09 OGYI-T-21756/09 OGYI-T-21756/05 OGYI-T-21756/05 OGYI-T-21756/05 OGYI-T-21756/04 OGYI-T-21756/03 OGYI-T-21756/03	SANDOZ HUNGARIA KFT	Hungary
Trimeluzine 35 mg	HU/H/0347	OGYI-T-21756/01 3564/2011/01	S.C. SANDOZ	Romania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
comprimate cu eliberare prelungită		3564/2011/02 3564/2011/03 3564/2011/04 3564/2011/05 3564/2011/06 3564/2011/07 3564/2011/09 3564/2011/10 3564/2011/10 3564/2011/11 3564/2011/12 3564/2011/13 3564/2011/14 3564/2011/15 3564/2011/16 3564/2011/16 3564/2011/18 3564/2011/19 3564/2011/19 3564/2011/20 3564/2011/20 3564/2011/21 3564/2011/21 3564/2011/21 3564/2011/22 3564/2011/23 3564/2011/24	S.R.L.	
Dimesar	HU/H/0347	18422	SANDOZ GMBH	Poland
Trimeluzine 35 mg tablete s podaljšanim sproščanjem	HU/H/0347	5363-I-868/12	LEK PHARMACEUTICALS D.D. LJUBLJANA	Slovenia
Trimetazidine Teva 35mg pailginto atpalaidavimo	HU/H/0344/001/DC	LT/1/10/2345/002-003	Teva Pharma B.V. Computerweg 10 3542 DR Ultrecht	Lithuania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
tabletės			Netherlands	
Trimetaratio Trimetazidinum 123ratio	national HU/H/0344/001/DC	9077 18077	Ratiopharm GmbH 123ratio Sp. Z. o.o.	Poland Poland
Trimetazidin- ratiopharm 35 mg Retardtabletten	DE/H/3522/001	86595.00.00	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, Germany	Germany
Trimetazidin ratiopharm retard 35 mg	HU/H/0344/001	41/0851/10-S	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, Germany	Slovakia
Trimetazidine Teva 35mg ilgstošās darbības tabletes	HU/H/0344/001	10-0639	Teva Pharma B.V.; Computerweg 10, 3542 DR Utrecht, The Netherlands	Latvia
Trimetazidin- ratiopharm 35 mg retard tabletta	HU/H/0344/001	OGYI-T-21552/01	ratiopharm GmbH; Graf-Arco-Str. 3, 89079 Ulm, Germany	Hungary
Trimetazidine Teva 35mg	HU/H/0344/001	734911	Teva Pharma B.V.; Computerweg 10, 3542 DR Utrecht, The Netherlands	Estonia
Trimetazidin Teva retard 35 mg, tablety s prodlouženým uvolňováním	HU/H/0344/001	83/908/10-C	Teva Pharmaceuticals CR, s.r.o.; Prague, Czech Republic	Czech Republic
Prezodone 20 mg coated tablets	national	20050114	Labormed Pharma S.A	Bulgaria
TevaTrim 35 mg prolonged-release	national	20110058	Teva Pharmaceuticals	Bulgaria

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
tablets			Bulgaria EOOD 15, Gogol str., floor 1, Sofia 1124, Bulgaria	
Trimetazidina Davur 20 mg comprimidos recubiertos EFG	national	64309	Laboratorios Davur S.L;. C/ Teide, 4. Parque Empresarial La Marina.	Spain
Trimetazidina ratiopharm 20 mg comprimidos recubiertos con película EFG	national	68578	ratiopharm Espana SA; C/Anabel Segura 11, Ed Albatros B, 1a planta, Alcobendas, 28108 Madrid, Spain	Spain
Trimetazidina Rimafar 20 mg comprimidos recubiertos EFG	national	64394	Laboratorios Rimafar S.L.; Zaragoza ES Polígono Industrial Malpica, c/C, 4 50016	Spain
TRIMETAZIDINE TEVA 20 mg/ml, solution buvable en gouttes	national	NL 23601	TEVA SANTE 100-110 Esplanade du Général de Gaulle 92931 PARIS LA DEFENSE CEDEX	France
Trimetazidina Mepha 20mg comprimidos revestidos	national	4747697, 4747796	Mepha	Portugal
Trimetazidina Anox	national	5434774, 5434808	ratiopharm	Portugal

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
35mg comprimidos de libertação prolongada				
Trimetazidina ratiopharm 35mg comprimidos de libertação prolongada	national	5297031, 5297049	ratiopharm	Portugal
Trimetazidina ratipharm 20mg comprimidos revestidos por película	national	5399589, 5399688	ratiopharm	Portugal
Trimetazidina Teva 20mg comprimidos revestidos	national	4883088, 4883187	Teva Pharma	Portugal
Trimetazidina Teva 35mg comprimidos de libertação prolongada	national	5185269, 5185517	Teva Pharma	Portugal
Trimetazidin- ratiopharm 20 mg	national	41/0196/04-S	ratiopharm GmbH Graf-Arco-Str. 3, 89079 Ulm, Germany	Slovakia
Trimetazidin - DemlGroup PR 35 mg	national	41/0875/10-S	Deml Group s.r.o., Brno, Czech Republic	Slovakia