



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2016
EMA/637689/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: trimetazidine

Procedure no.: EMEA/H/N/PSR/J/0002



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
Mezitan 35 mg Módosított hatóanyag-leadású Tabl	NA	OGYI-T-21279/01	Aramis Pharma Kft.	Hungary
Trimetacor 35 mg Tablets	NA	MA No. II-16000 Reg. No. 20110715	Alvogen IPCo S.ar.l	Bulgaria
Trimetazidina LPH 20mg comprimate Filmate	NA	6001/2005/01-02-03- 04	Labormed Pharma SA	Romania
Trimetazidina LPH 35mg comprimate cu eliberare modificata	NA	5371/2005/01-02-03	Labormed Pharma SA	Romania
Trimetazidine Actavis	EE/H/0134/001	691010	Actavis Group PTC ehf.	Estonia
Trimetazidin Actavis 35 mg	EE/H/0134/001	83/578/10-C	Actavis Group PTC ehf.	Czech Republic
Trimetazidine Actavis 35 mg ilgstošas darbības tabletes	EE/H/0134/001	10-0390	Actavis Group PTC ehf.	Latvia
Trimetazidine Actavis 35 mg modifikuoto atpalaidavimo tabletes	EE/H/0134/001	LT/1/10/2146/001	Actavis Group PTC ehf.	Lithuania
Vascotasin	EE/H/0134/001	20100413	Actavis Group PTC ehf.	Bulgaria

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Vascotasin 35 mg módosított hatóanyagleadású tablettá	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	HU/H/0310/001/MR	20110539	Gedeon Richter Plc.	Bulgaria
Protevasc 35 mg	HU/H/0310/001/MR	83/686/11-C	Gedeon Richter Plc.	Czech Republic
Moduxin MR 35 mg	HU/H/0310/001/MR	OGYI-T-20603/04 (180x); OGYI-T-20603/03 (120x); OGYI-T-20603/02 (60x); OGYI-T-20603/05 (30x)	Gedeon Richter Plc.	Hungary
Moduxin 35 mg	HU/H/0310/001/MR	11-0503	Gedeon Richter Plc.	Latvia
Moduxin 35 mg	HU/H/0310/001/MR	LT/1/11/2616/001 (60x); LT/1/11/2616/003 (180x); LT/1/11/2616/002 (120x)	Gedeon Richter Plc.	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

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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

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Comprimido de libertacao prolongada			Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, No 11, 3o, 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

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tableta		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, 3418/2011/08, 3418/2011/09, 3418/2011/10, 3418/2011/11, 3418/2011/12, 3418/2011/13, 3418/2011/14, 3418/2011/15, 3418/2011/16, 3418/2011/17, 3418/2011/18, 3418/2011/19, 3418/2011/20,	Mylan S.A.S	Romania

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Trimetazidin Mylan 35 mg	DE/H/2653/001/DC	3418/2011/21, 3418/2011/22, 3418/2011/23, 3418/2011/24 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 tableta	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-21756/18 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-21756/11 OGYI-T-21756/10 OGYI-T-21756/09 OGYI-T-21756/08 OGYI-T-21756/07 OGYI-T-21756/06 OGYI-T-21756/05 OGYI-T-21756/04 OGYI-T-21756/03 OGYI-T-21756/02 OGYI-T-21756/01	SANDOZ HUNGARIA KFT	Hungary
Trimeluzine 35 mg	HU/H/0347	3564/2011/01	S.C. SANDOZ	Romania

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comprimate cu eliberare prelungită		3564/2011/02	S.R.L.	
		3564/2011/03		
		3564/2011/04		
		3564/2011/05		
		3564/2011/06		
		3564/2011/07		
		3564/2011/08		
		3564/2011/09		
		3564/2011/10		
		3564/2011/11		
		3564/2011/12		
		3564/2011/13		
		3564/2011/14		
		3564/2011/15		
		3564/2011/16		
		3564/2011/17		
		3564/2011/18		
		3564/2011/19		
		3564/2011/20		
		3564/2011/21		
		3564/2011/22		
		3564/2011/23		
		3564/2011/24		
		Dimesar		
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 Utrecht	Lithuania

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tabletēs			Netherlands	
Trimetaratio	national	9077	Ratiopharm GmbH	Poland
Trimetazidinum 123ratio	HU/H/0344/001/DC	18077	123ratio Sp. Z. o.o.	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 tableta	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

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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

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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