



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 February 2016  
EMA/283098/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: trimetazidine

Procedure no.: EMEA/H/N/PSR/0001



Member state	Marketing authorisation holder	Product name	Strength	Pharmaceutical Form	Route of administration
CYPRUS	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20MG	20MG	FILM-COATED TABLET	ORAL USE
DENMARK	LES LABORATOIRES SERVIER (SURESNES)	Vastarel	20MG	FILM-COATED TABLET	ORAL USE
FRANCE	BIOGARAN	TRIMETAZIDINE BIOGARAN 20MG, comprimé pelliculé	20MG	FILM-COATED TABLET	ORAL USE
FRANCE	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20MG, comprimé pelliculé	20MG	FILM-COATED TABLET	ORAL USE
GREECE	SERVIER HELLAS	VASTAREL 20 mg, επικαλυμμένο με λεπτό υμένιο δισκίο	20MG	FILM-COATED TABLET	ORAL USE
IRELAND	SERVIER LABORATORIES (IRELAND) LTD	VASTAREL 20 MG FILM-COATED TABLETS	20MG	FILM-COATED TABLET	ORAL USE
ITALY	IST. FARMACO BIOLOGICO SRL STRODER	VASTAREL 20 mg compresse rivestite	20MG	FILM-COATED TABLET	ORAL USE
LUXEMBOURG	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20MG, comprimé pelliculé	20MG	FILM-COATED TABLET	ORAL USE
MALTA	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20 mg, film-coated tablets	20MG	FILM-COATED TABLET	ORAL USE
PORTUGAL	SERVIER PORTUGAL, Especialidades Farmacêuticas, Lda.	VASTAREL	20MG	FILM-COATED TABLET	ORAL USE
ROMANIA	LES LABORATOIRES SERVIER (SURESNES)	Preductal 20 mg comprimate filmate	20MG	FILM-COATED TABLET	ORAL USE
SPAIN	DANVAL S.A.	IDAPTAN 20 mg comprimidos recubiertos con película	20MG	FILM-COATED TABLET	ORAL USE
CYPRUS	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20MG/ML	20MG/ML	ORAL DROPS, SOLUTION	ORAL USE
FRANCE	BIOGARAN	TRIMETAZIDINE BIOGARAN 20MG/ML, solution buvable, gouttes	20MG/ML	ORAL DROPS, SOLUTION	ORAL USE
FRANCE	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 20MG/ML, solution buvable, gouttes	20MG/ML	ORAL DROPS, SOLUTION	ORAL USE
GREECE	SERVIER HELLAS	VASTAREL 20 mg/ml, πόσιμες σταγόνες, διάλυμα	20MG/ML	ORAL DROPS, SOLUTION	ORAL USE
PORTUGAL	SERVIER PORTUGAL, Especialidades Farmacêuticas, Lda.	VASTAREL	20MG/ML	ORAL DROPS, SOLUTION	ORAL USE

Member State	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
AUSTRIA	SERVIER AUSTRIA GMBH	Vastarel 35 mg - Filmtabletten mit veränderter Wirkstofffreisetzung	35MG	PROLONGED-RELEASE TABLET	ORAL USE
BULGARIA	LES LABORATOIRES SERVIER (SURESNES)	ПРЕДУКТАЛ MR 35 mg таблетки с изменено освобождаване	35MG	PROLONGED-RELEASE TABLET	ORAL USE
CROATIA	SERVIER PHARMA D.O.O -CROATIA	PREDUCTAL MR 35 mg tablete s prilagođenim oslobađanjem	35MG	PROLONGED-RELEASE TABLET	ORAL USE
CYPRUS	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 35MG	35MG	PROLONGED-RELEASE TABLET	ORAL USE
CZECH REPUBLIC	LES LABORATOIRES SERVIER (SURESNES)	PREDUCTAL MR	35MG	PROLONGED-RELEASE TABLET	ORAL USE
EMA	SERVIER HONG KONG LTD	VASTAREL	35MG	FILM-COATED TABLET	ORAL USE
ESTONIA	LES LABORATOIRES SERVIER (SURESNES)	Preductal MR, 35 mg toimealnet modifitseeritud vabastavad tabletid	35MG	PROLONGED-RELEASE TABLET	ORAL USE
ESTONIA	LES LABORATOIRES SERVIER (SURESNES)	TRIMETAZIDINE MR SERVIER	35MG	PROLONGED-RELEASE TABLET	ORAL USE
FRANCE	BIOGARAN	TRIMETAZIDINE BGR 35MG, comprimé pelliculé à libération modifiée	35MG	PROLONGED-RELEASE TABLET	ORAL USE
FRANCE	BIOGARAN	TRIMETAZIDINE BIOGARAN 35MG, comprimé pelliculé à libération modifiée	35MG	PROLONGED-RELEASE TABLET	ORAL USE
FRANCE	BIOGARAN	TRIMETAZIDINE EG 35MG, comprimé pelliculé à libération modifiée	35MG	PROLONGED-RELEASE TABLET	ORAL USE
FRANCE	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 35MG, comprimé pelliculé à libération modifiée	35MG	PROLONGED-RELEASE TABLET	ORAL USE
GREECE	SERVIER HELLAS	VASTAREL 35 mg, διακρίο ελεγχόμενης αποδέσμευσης	35MG	PROLONGED-RELEASE TABLET	ORAL USE
HUNGARY	EGIS PHARMACEUTICALS PLC	Adexor MR 35 mg módosított hatóanyagleadású filmtabletta	35MG	PROLONGED-RELEASE TABLET	ORAL USE
HUNGARY	LES LABORATOIRES SERVIER (SURESNES)	Preductal MR 35 mg módosított hatóanyagleadású filmtabletta	35MG	PROLONGED-RELEASE TABLET	ORAL USE
IRELAND	SERVIER LABORATORIES (IRELAND) LTD	VASTAREL 35MG PROLONGED-RELEASE TABLETS	35MG	PROLONGED-RELEASE TABLET	ORAL USE
LATVIA	LES LABORATOIRES SERVIER (SURESNES)	Preductal MR 35mg ilgstošās darbības apvalkotās tabletes	35MG	PROLONGED-RELEASE TABLET	ORAL USE
LATVIA	LES LABORATOIRES SERVIER (SURESNES)	Trimetazidine MR Servier 35mg ilgstošās darbības apvalkotās tabletes	35MG	PROLONGED-RELEASE TABLET	ORAL USE
LITHUANIA	LES LABORATOIRES SERVIER (SURESNES)	PREDUCTAL MR 35 mg modifikuoto atpalaidavimo plėvele dengtos tabletės	35MG	PROLONGED-RELEASE TABLET	ORAL USE
LITHUANIA	LES LABORATOIRES SERVIER (SURESNES)	Trimetazidine MR Servier 35 mg modifikuoto atpalaidavimo plėvele dengtos tabletės	35MG	PROLONGED-RELEASE TABLET	ORAL USE
LUXEMBOURG	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL 35MG, comprimé pelliculé à libération modifiée	35MG	PROLONGED-RELEASE TABLET	ORAL USE
MALTA	LES LABORATOIRES SERVIER (SURESNES)	VASTAREL MR 35 mg, modified release film-coated tablets	35MG	PROLONGED-RELEASE TABLET	ORAL USE
POLAND	ANPHARM PRZEDSIĘBIORSTWO FARMACEUTYCZNE SPÓŁKA AKCYJNA	PREDUCTAL MR	35MG	PROLONGED-RELEASE TABLET	ORAL USE
PORTUGAL	LES LABORATOIRES SERVIER (SURESNES)	TACIREL LM	35MG	PROLONGED-RELEASE TABLET	ORAL USE
PORTUGAL	SERVIER PORTUGAL, Especialidades Farmacêuticas, Lda.	VASTAREL LM	35MG	PROLONGED-RELEASE TABLET	ORAL USE
ROMANIA	LES LABORATOIRES SERVIER (SURESNES)	PREDUCTAL MR 35 mg comprimate cu eliberare modificată	35MG	PROLONGED-RELEASE TABLET	ORAL USE
SLOVAKIA	LES LABORATOIRES SERVIER (SURESNES)	PREDUCTAL MR	35MG	PROLONGED-RELEASE TABLET	ORAL USE
SLOVENIA	SERVIER PHARMA D.O.O	PREDUCTAL MR 35 mg filmsko obložene tablete s prirejenim sproščanjem	35MG	PROLONGED-RELEASE TABLET	ORAL USE