

## **Annex I**

**List of the names, pharmaceutical form(s), strength(s) of the medicinal product(s), route(s) of administration, marketing authorisation holder(s) in the member states**

| <b>Member State<br/>EU/EEA</b> | <b>Marketing authorisation holder</b>                                                | <b>Product name</b>                                                          | <b>Strength</b> | <b>Pharmaceutical form</b>              | <b>Route of administration</b> |
|--------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------|-----------------------------------------|--------------------------------|
| Austria                        | Servier Austria GmbH<br>Mariahilfer Straße 20/5<br>Vienna 1070<br>Austria            | Vastarel 35 mg -<br>Filmtabletten mit<br>veränderter<br>Wirkstofffreisetzung | 35 mg           | Modified-release film-<br>coated tablet | Oral use                       |
| Bulgaria                       | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France        | Predictal MR                                                                 | 35 mg           | Modified-release tablet                 | Oral use                       |
| Bulgaria                       | Medica AD<br>Industrial area<br>Sandanski 2800<br>Bulgaria                           | Prectazidine MR                                                              | 35 mg           | Modified-release tablet                 | Oral use                       |
| Bulgaria                       | Actavis Group PTC ehf.,<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland     | Vascotasin                                                                   | 35 mg           | Modified-release tablet                 | Oral use                       |
| Bulgaria                       | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>89079 Ulm<br>Germany                       | Trimetazidine-ratiopharm                                                     | 35 mg           | Modified-release tablet                 | Oral use                       |
| Bulgaria                       | S.C. Labormed Pharma S.A.<br>44 B, Theodor Pallady,<br>sector 3 Bucharest<br>Romania | Predozone                                                                    | 20 mg           | Coated tablet                           | Oral use                       |
| Bulgaria                       | Sopharma AD<br>16 Iliensko shosse str.<br>1220 Sofia<br>Bulgaria                     | Trimductal                                                                   | 20 mg           | Film-coated tablet                      | Oral use                       |
| Bulgaria                       | Mylan S.A.S.<br>117 Allée des Parcs 69800<br>Saint Priest<br>France                  | Trimetazigen MR                                                              | 35 mg           | Prolonged - release tablet              | Oral use                       |

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| Bulgaria       | Glenmark Pharmaceuticals<br>S.r.o.<br>Hvezdova 1716/2b<br>Prague 4, 140 78<br>Czech Republic       | Apstar                     | 35 mg   | Modified-release tablet             | Oral use |
| Bulgaria       | Gedeon Richter Plc.<br>Gyomroi ut 19-21<br>H- 1103 Budapest<br>Hungary                             | Moduxin MR                 | 35 mg   | Prolonged release tablets           | Oral use |
| Bulgaria       | Sandoz d.d.<br>Verovskova 57<br>1000 Ljubljana<br>Slovenia                                         | Trimeluzine                | 35 mg   | Modified-release tablet             | Oral use |
| Cyprus         | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | VASTAREL 20 mg             | 20mg    | Film-coated tablet                  | Oral use |
| Cyprus         | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | VASTAREL                   | 20mg/ml | Oral drops                          | Oral use |
| Cyprus         | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | VASTAREL MR                | 35mg    | Modified-release film-coated tablet | Oral use |
| Czech Republic | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | PREDUCTAL MR               | 35 mg   | Modified-release tablet             | Oral use |
| Czech Republic | Actavis Group PTC ehf.,<br>Hafnarfjörður<br>Reykjavíkurvegur 76-78<br>220 Hafnarfjörður<br>Iceland | TRIMETAZIDIN ACTAVIS 35 MG | 35 mg   | Modified-release tablet             | Oral use |
| Czech Republic | Mylan S.A.S<br>117 Allée des Parcs<br>69 800, Saint-Priest<br>France                               | TRIMETAZIDIN MYLAN 35 MG   | 35mg    | Prolonged-release tablet            | Oral use |

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| Czech Republic | SANDOZ s.r.o.<br>U Nákladového nádraží 10<br>130 00 Prague<br>Czech Republic             | TRIMETAZIDIN SANDOZ 35 MG                        | 35mg  | Prolonged-release tablet | Oral use |
| Czech Republic | Glenmark Pharmaceuticals s.r.o<br>Hvezdova 1716/2b<br>Prague 4, 140 78<br>Czech Republic | PORTORA 35 MG TABLETY S PRODLOUŽENÝM UVOLŇOVÁNÍM | 35 mg | Prolonged-release tablet | Oral use |
| Czech Republic | Teva Pharmaceuticals CR, s.r.o.<br>Radlická 3185/1c<br>150 00 Prague 5<br>Czech Republic | TRIMETAZIDIN TEVA RETARD 35 MG                   | 35 mg | Prolonged-release tablet | Oral use |
| Denmark        | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France             | Vastarel                                         | 20 mg | Film-coated tablet       | Oral use |
| Estonia        | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France             | TRIMETAZIDINE MR SERVIER                         | 35mg  | Modified-release tablet  | Oral use |
| Estonia        | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France             | PREDUCTAL MR                                     | 35mg  | Modified-release tablet  | Oral use |
| Estonia        | Actavis Group PTC ehf<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Island            | TRIMETAZIDINE ACTAVIS                            | 35mg  | Modified-release tablet  | Oral use |
| Estonia        | Teva Pharma B.V.<br>Computerweg 10<br>3542 DR Utrecht<br>The Netherlands                 | TRIMETAZIDINE TEVA 35 MG                         | 35 mg | Film-coated tablet       | Oral use |
| Estonia        | Sandoz d.d.<br>Verovskova 57<br>SI-1000 Ljubljana<br>Slovenia                            | ZIDMETIN                                         | 35 mg | Prolonged-release tablet | Oral use |

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| France | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France | TRIMETAZIDINE ALMUS    | 20 mg    | Film-coated tablet                  | Oral use |
| France | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France | TRIMETAZIDINE BIOGARAN | 20 mg    | Film-coated tablet                  | Oral use |
| France | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France | TRIMETAZIDINE BIOGARAN | 20 mg/ml | Oral solution                       | Oral use |
| France | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France | TRIMETAZIDINE BIOGARAN | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | CRISTERS<br>22 quai Gallieni<br>92150 Suresnes<br>France                      | TRIMETAZIDINE CRISTERS | 20 mg    | Film-coated tablet                  | Oral use |
| France | QUALIMED<br>117, allée des Parcs<br>69800 Saint-Priest<br>France              | TRIMETAZIDINE QUALIMED | 20 mg/ml | Oral drops, solution                | Oral use |
| France | QUALIMED<br>117, allée des Parcs<br>69800 Saint-Priest<br>France              | TRIMETAZIDINE QUALIMED | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France  | VASTAREL               | 20 mg    | Film-coated tablet                  | Oral use |
| France | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France  | VASTAREL               | 20 mg/ml | Oral drops, solution                | Oral use |

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| France | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | VASTAREL                 | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | VENIPHARM<br>4, bureaux de la Colline<br>92213 Saint-Cloud<br>France                               | TRANETIZ                 | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | VENIPHARM<br>4, bureaux de la Colline<br>92213 Saint-Cloud<br>France                               | TRIGEMAX                 | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex<br>France                      | TRIMETAZIDINE BGR        | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | CLL PHARMA<br>Nice Premier - Arénas<br>455, Promenade des Anglais<br>06299 Nice Cedex 03<br>France | TRIMETAZIDINE CLL PHARMA | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | SOCIÉTÉ IPSOR<br>GENERIQUES - IGEN<br>18, avenue des Champs-Élysées<br>75008 Paris<br>France       | TRIMETAZIDINE IGEN       | 20 mg/ml | Oral drops, solution                | Oral use |
| France | LABORATOIRES IPSOR<br>18 Avenue des Champs Elysees<br>75008 Paris<br>France                        | TRIMETAZIDINE IPSOR      | 20 mg    | Film-coated tablet                  | Oral use |
| France | LABORATOIRES IPSOR<br>18 Avenue des Champs Elysees<br>75008 Paris<br>France                        | TRIMETAZIDINE IPSOR      | 20 mg/ml | Oral drops, solution                | Oral use |

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| France | PLUS PHARMACIE SA<br>26, boulevard Paul Vaillant-Couturier<br>94200 Ivry-sur-Seine<br>France                                       | TRIMETAZIDINE ISOMED         | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | CLL PHARMA<br>Nice Premier - Arénas<br>455, Promenade des Anglais<br>06299 Nice Cedex 03<br>France                                 | TRIMETAZIDINE MILGEN         | 20 mg    | Film-coated tablet                  | Oral use |
| France | CLL PHARMA<br>Nice Premier - Arénas<br>455, Promenade des Anglais<br>06299 Nice Cedex 03<br>France                                 | TRIMETAZIDINE MILGEN         | 20 mg/ml | Oral drops, solution                | Oral use |
| France | RATIOPHARM GMBH<br>Graf Arco Strasse 3<br>89079 Ulm<br>Germany                                                                     | TRIMETAZIDINE<br>RATIOPHARM  | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | SUBSTIPHARM<br>8, rue Bellini<br>75116 Paris<br>France                                                                             | TRIMETAZIDINE<br>SUBSTIPHARM | 20 mg/ml | Oral drops, solution                | Oral use |
| France | ZYDUS FRANCE<br>25, rue des Peupliers<br>ZAC Les Hautes Pâtures -<br>Parc d'Activités des<br>Peupliers<br>92000 Nanterre<br>France | TRIMETAZIDINE ZYDUS          | 20 mg    | Film-coated tablet                  | Oral use |
| France | ZYDUS FRANCE<br>25, rue des Peupliers<br>ZAC Les Hautes Pâtures -<br>Parc d'Activités des<br>Peupliers<br>92000 Nanterre<br>France | TRIMETAZIDINE ZYDUS          | 20 mg/ml | Oral solution                       | Oral use |

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|--------|------------------------------------------------------------------------------------------------|------------------------|----------|-------------------------------------|----------|
| France | VENIPHARM<br>4, bureaux de la Colline<br>92213 Saint-Cloud<br>France                           | TRIMEVENI              | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | TEVA SANTE<br>Le Palatin 1<br>1 cours du Triangle<br>92936 Paris la Défense<br>Cedex<br>France | TRIMETAZIDINE TEVA     | 20 mg/ml | Oral solution                       | Oral use |
| France | TEVA SANTE<br>Le Palatin 1<br>1 cours du Triangle<br>92936 Paris la Défense<br>Cedex<br>France | TRIMETAZIDINE TEVA     | 20 mg    | Film-coated tablet                  | Oral use |
| France | TEVA SANTE<br>Le Palatin 1<br>1 cours du Triangle<br>9296 Paris la Défense<br>Cedex<br>France  | TRIMETAZIDINE TEVA     | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | SANOFI AVENTIS FRANCE<br>1-13, boulevard Romain<br>Rolland<br>75014 Paris<br>France            | TRIMETAZIDINE WINTHROP | 20 mg    | Film-coated tablet                  | Oral use |
| France | SANOFI AVENTIS FRANCE<br>1-13, boulevard Romain<br>Rolland<br>75014 Paris<br>France            | TRIMETAZIDINE WINTHROP | 20 mg/ml | Oral solution                       | Oral use |
| France | SANOFI AVENTIS FRANCE<br>1-13, boulevard Romain<br>Rolland<br>75014 Paris<br>France            | TRIMETAZIDINE WINTHROP | 35 mg    | Modified-release film coated tablet | Oral use |
| France | AJC INVEST<br>6, rue de la Rochefoucauld<br>16000 Angoulême<br>France                          | RIMETAZE               | 20mg     | Film coated tablet                  | Oral use |



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| France | AJC INVEST<br>6, rue de la Rochefoucauld<br>16000 Angoulême<br>France                            | RIMETAZE               | 20 mg/ml | Oral solution                       | Oral use |
| France | MYLAN SAS<br>117, allée des Parcs<br>69800 Saint-Priest<br>France                                | TRIMETAZIDINE MYLAN    | 20 mg    | Film coated tablet                  | Oral use |
| France | MYLAN SAS<br>117, allée des Parcs<br>69800 Saint-Priest<br>France                                | TRIMETAZIDINE MYLAN    | 20 mg/ml | Oral solution                       | Oral use |
| France | MYLAN SAS<br>117, allée des Parcs<br>69800 Saint-Priest<br>France                                | TRIMETAZIDINE MYLAN    | 35 mg    | Modified-release film-coated tablet | Oral use |
| France | SANDOZ<br>49, avenue Georges<br>Pompidou<br>92300 Levallois-Perret<br>France                     | TRIMETAZIDINE SANDOZ   | 20 mg    | Film coated tablet                  | Oral use |
| France | SANDOZ<br>49, avenue Georges<br>Pompidou<br>92300 Levallois-Perret<br>France                     | TRIMETAZIDINE SANDOZ   | 20 mg/ml | Oral solution                       | Oral use |
| France | ACTAVIS France<br>La Boursidière Centre<br>d'Affaires 92357 Le Plessis<br>Robinson<br>France     | TRIMETAZIDINE ACTAVIS  | 20 mg    | Film coated tablet                  | Oral use |
| France | QUALIMED<br>117, allée des Parcs<br>69800 Saint-Priest<br>France                                 | TRIMETAZIDINE QUALIMED | 20 mg    | Film coated tablet                  | Oral use |
| France | PLUS PHARMACIE SA<br>26, boulevard Paul Vaillant-<br>Couturier<br>94200 Ivry-sur-Seine<br>France | TRIMETAZIDINE ISOMED   | 20 mg    | Coated tablet                       | Oral use |

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| France | EG LABO - LABORATOIRES<br>EUROGENERICS<br>"Le Quintet" - bâtiment A<br>12, rue Danjou<br>92517 Boulogne Billancourt<br>Cedex<br>France | TRIMETAZIDINE EG            | 20 mg    | Film coated tablet                      | Oral use |
| France | EG LABO - LABORATOIRES<br>EUROGENERICS<br>"Le Quintet" - bâtiment A<br>12, rue Danjou<br>92517 Boulogne Billancourt<br>Cedex<br>France | TRIMETAZIDINE EG            | 20 mg/ml | Oral solution                           | Oral use |
| France | EG LABO - LABORATOIRES<br>EUROGENERICS<br>"Le Quintet" - bâtiment A<br>12, rue Danjou<br>92517 Boulogne Billancourt<br>Cedex<br>France | TRIMETAZIDINE EG            | 35 mg    | Modified-release film-<br>coated tablet | Oral use |
| France | ARROW GENERIQUES<br>26, avenue Tony Garnier<br>69007 Lyon<br>France                                                                    | TRIMETAZIDINE<br>ARROW      | 20 mg    | Film coated tablet                      | Oral use |
| France | ARROW GENERIQUES<br>26, avenue Tony Garnier<br>69007 Lyon<br>France                                                                    | TRIMETAZIDINE<br>ARROW      | 20 mg/ml | Oral solution                           | Oral use |
| France | RATIOPHARM GMBH<br>Graf Arco Strasse 3<br>89079 Ulm<br>Germany                                                                         | TRIMETAZIDINE<br>RATIOPHARM | 20 mg    | Coated tablet                           | Oral use |
| France | RATIOPHARM GMBH<br>Graf Arco Strasse 3<br>89079 Ulm<br>Germany                                                                         | TRIMETAZIDINE<br>RATIOPHARM | 20 mg/ml | Oral solution                           | Oral use |

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| France  | SANDOZ<br>49, avenue Georges<br>Pompidou<br>92300 Levallois-Perret<br>France                                                                            | TRIMETAZIDINE SANDOZ                             | 35 mg     | modified-release film-<br>coated tablet | Oral use |
| Germany | ratiopharm GmbH<br>Graf-Arco-Str. 3<br>89079 Ulm<br>Germany                                                                                             | Trimetazidin-ratiopharm 35<br>mg Retardtabletten | 35 mg     | Prolonged release tablet                | Oral use |
| Germany | Mepha Investigacao,<br>Desenvolvimento e<br>Fabricacao Farmaceutica,<br>Lda.<br>Lagoas Park, Edificio 5A,<br>Piso 2<br>2740-298 Porto Salvo<br>Portugal | Mephatrim 35 mg<br>Retardtabletten               | 35 mg     | Prolonged release tablet                | Oral use |
| Greece  | HELP ABEE,<br>Valaoritou 10<br>Metamorfosi Attikis 14452<br>Greece                                                                                      | NOVAZIDINE                                       | 20mg/ml   | Oral drops, solution                    | Oral use |
| Greece  | FOINIXFARM EPE<br>Dervenakion 38 & Sachini<br>Gerakas 15344<br>Greece                                                                                   | ZIDIN                                            | 20mg/ml   | Oral drops, solution                    | Oral use |
| Greece  | SERVIER HELLAS<br>PHARMACEUTICALS Ltd,<br>Ethnikis Antistaseos 72 &<br>Agamemnonos<br>Greece                                                            | VASTAREL                                         | 20 mg/tab | Film-coated tablet                      | Oral use |
| Greece  | SERVIER HELLAS<br>PHARMACEUTICALS Ltd,<br>Ethnikis Antistaseos 72 &<br>Agamemnonos<br>Greece                                                            | VASTAREL                                         | 20mg/ml   | Oral drops, solution                    | Oral use |
| Greece  | SERVIER HELLAS<br>PHARMACEUTICALS Ltd,<br>Ethnikis Antistaseos 72 &<br>Agamemnonos<br>Greece                                                            | VASTAREL                                         | 35 mg/tab | Controlled release tablet               | Oral use |

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| Hungary | Richter Gedeon nyrt.<br>Gyömrői út 19-21.<br>1103 Budapest<br>Hungary                               | Moduxin MR                                                  | 35 mg | Prolonged-release tablet            | Oral use |
| Hungary | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                       | Predictal MR                                                | 35 mg | Modified-release film-coated tablet | Oral use |
| Hungary | EGIS Gyógyszergyár nyrt.<br>Keresztúri út 30-38.<br>1106 Budapest<br>Hungary                        | Adexor MR                                                   | 35 mg | Modified-release film-coated tablet | Oral use |
| Hungary | Glenmark Pharmaceuticals<br>S.r.o<br>Hvezdova 1716/2b<br>Prague 4, 140 78<br>Czech Republic         | APSTAR 35 mg retard<br>tabletta                             | 35 mg | Prolonged-release tablet            | Oral use |
| Hungary | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>89079 Ulm<br>Germany                                      | TRIMETAZIDIN-<br>RATIOPHARM 35 mg retard<br>tabletta        | 35 mg | Prolonged-release tablet            | Oral use |
| Hungary | Mylan S.A.S<br>117 Allee des Parcs<br>69800 Saint Priest<br>France                                  | TRIMETAZIDINE MYLAN 35<br>mg retard tablettá                | 35 mg | Prolonged-release tablet            | Oral use |
| Hungary | Actavis Group PTC ehf.,<br>Hafnarfjörður<br>Reykjavíkurevegur 76-78<br>220 Hafnarfjörður<br>Iceland | VASCOTASIN 35 mg<br>módosított<br>hatóanyagleadású tablettá | 35 mg | modified release tablet             | Oral use |
| Hungary | Sandoz Hungária Kft.<br>1114 Budapest<br>Bartók Béla út 43-47.<br>Magyarország<br>Hungary           | TRIMETAZIDINE SANDOZ 35<br>mg retard tablettá               | 35 mg | Prolonged-release tablet            | Oral use |

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| Ireland | Servier Laboratories<br>(Ireland) Ltd<br>First Floor, Block 2<br>West Pier Business Campus<br>Old Dunleary Road,<br>Dun Laoghaire<br>Dublin<br>Ireland | Vastarel                                                        | 20mg  | Film-coated tablet                   | Oral use |
| Ireland | Servier Laboratories<br>(Ireland) Ltd<br>First Floor, Block 2<br>West Pier Business Campus<br>Old Dunleary Road,<br>Dun Laoghaire<br>Dublin<br>Ireland | Trimetazidine                                                   | 35mg  | Prolonged-release film-coated tablet | Oral use |
| Ireland | Servier Laboratories<br>(Ireland) Ltd<br>First Floor, Block 2<br>West Pier Business Campus<br>Old Dunleary Road,<br>Dun Laoghaire<br>Dublin<br>Ireland | Vastarel                                                        | 35mg  | Prolonged-release film-coated tablet | Oral use |
| Italy   | Istituto Farmaco Biologico<br>Stroder S.R.L.<br>Via di Ripoli, 207V - 50126<br>Firenze<br>Italy                                                        | VASTAREL                                                        | 20 MG | Coated tablet                        | Oral use |
| Latvia  | Gedeon Richter Plc.<br>H-1103 Budapest<br>Gyömrői út 19-21<br>Hungary                                                                                  | Moduxin 35 mg ilgstošās<br>darbības tabletes                    | 35 mg | Prolonged-release tablet             | Oral use |
| Latvia  | Actavis Group PTC ehf.,<br>Reykjavíkurvegi 76-78,<br>220 Hafnarfjörður<br>Iceland                                                                      | Trimetazidine Actavis 35 mg<br>ilgstošās darbības tabletes      | 35 mg | Modified-release tablet              | Oral use |
| Latvia  | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                                                           | Predictal MR 35 mg<br>ilgstošās darbības<br>apvalkotās tabletes | 35 mg | Modified-release tablet              | Oral use |

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| Latvia     | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France     | Trimetazidine MR Servier 35 mg ilgstošās darbības apvalkotās tabletes | 35 mg   | Modified-release tablet                    | Oral use |
| Latvia     | Teva Pharma B.V.<br>Computerweg 10, 3542 DR Utrecht<br>The Netherlands           | Trimetazidine Teva 35 mg ilgstošās darbības tabletes                  | 35 mg   | Prolonged-release tablet                   | Oral use |
| Latvia     | Sandoz d.d<br>Verovskova 57,<br>SI-1000 Ljubljana<br>Slovenia                    | Zidmetin 35 mg ilgstošās darbības tabletes                            | 35 mg   | Modified-release tablet                    | Oral use |
| Lithuania  | Sandoz d.d<br>Verovskova 57,<br>SI-1000 Ljubljana<br>Slovenia                    | Zidmetin                                                              | 35 mg   | Prolonged-release tablet                   | Oral use |
| Lithuania  | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France    | Preductal MR                                                          | 35 mg   | Modified-release film-coated tablet tablet | Oral use |
| Lithuania  | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France    | Trimetazidine MR Servier                                              | 35 mg   | Modified-release film-coated tablet tablet | Oral use |
| Lithuania  | Teva Pharma B.V.<br>Computerweg 10 3542 DR Utrecht<br>The Netherlands            | Trimetazidine-Teva                                                    | 35 mg   | Prolonged-release tablet                   | Oral use |
| Lithuania  | Actavis Group PTC ehf.,<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Trimetazidine Actavis                                                 | 35 mg   | Modified-release tablet                    | Oral use |
| Luxembourg | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France    | Vastarel-20                                                           | 20mg    | Coated tablet                              | Oral use |
| Luxembourg | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France    | Vastarel                                                              | 20mg/ml | Drops                                      | Oral use |

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| Luxembourg | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                   | Vastarel-35       | 35mg  | Prolonged-release tablet                | Oral use |
| Malta      | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                  | VASTAREL 20 mg    | 20 mg | Film-coated tablet                      | Oral use |
| Malta      | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                  | VASTAREL MR       | 35 mg | Modified release film<br>coated tablet  | Oral use |
| Poland     | Ethifarm Sp. z o. o.<br>ul. Hiacyntowa 39<br>60-175 Poznań<br>Poland                                           | Cyto-Protectin MR | 35mg  | Prolonged-release tablet                | Oral use |
| Poland     | Przedsiębiorstwo<br>Farmaceutyczne<br>LEK-AM Sp. z o.o.<br>Ostrzykowitzna 14A<br>05-170 Zakroczym<br>Poland    | Trimeductan MR    | 35mg  | Prolonged-release tablet                | Oral use |
| Poland     | Pabianickie Zakłady<br>Farmaceutyczne Polfa S.A.<br>Marszałka J. Piłsudskiego 5,<br>95-200 Pabianice<br>Poland | Metazydyna        | 20 mg | Film-coated tablet                      | Oral use |
| Poland     | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                  | Preductal         | 20 mg | Film-coated tablet                      | Oral use |
| Poland     | ANPHARM Przedsiębiorstwo<br>Farmaceutyczne S.A.<br>ul. Annopol 6B<br>03-236 Warszawa<br>Poland                 | Preductal MR      | 35 mg | Modified-release film-<br>coated tablet | Oral use |

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| Poland   | Gedeon Richter Polska Sp. z o.o.<br>Graniczna str. 35<br>05-825 Grodzisk Mazowiecki<br>Poland                              | Protevasc SR                | 35 mg | Modified-release film-coated tablet | Oral use |
| Poland   | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>Ulm, 89079<br>Germany                                                            | Trimetataratio              | 20 mg | Film-coated tablet                  | Oral use |
| Poland   | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>Ulm, 89079<br>Germany                                                            | Trimetazidine-ratiopharm PR | 35 mg | Prolonged-release tablet            | Oral use |
| Poland   | Ethifarm Sp. z o. o.<br>ul. Hiacyntowa 39<br>60-175 Poznań<br>Poland                                                       | Cyto-Protectin MR           | 35mg  | Prolonged-release tablet            | Oral use |
| Poland   | Glenmark Pharmaceuticals s.r.o.<br>Hvezdova 1716/2b<br>Praga 4<br>CZ-140 78<br>Czech Republic                              | Portora                     | 35 mg | Prolonged-release tablet            | Oral use |
| Poland   | Zentiva, k.s.<br>U kabelovny 130<br>Praga 10, Dolni Mecholupy<br>10237 Dolni Mecholupy<br>Czech Republic                   | Trimedal                    | 35 mg | Prolonged-release tablet            | Oral use |
| Poland   | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria                                                              | Dimesar                     | 35 mg | Prolonged-release tablet            | Oral use |
| Portugal | Servier Portugal - Especialidades Farmacêuticas, Lda.<br>Av. António Augusto de Aguiar, 128<br>1069-133 Lisboa<br>Portugal | Vastarel                    | 20 mg | Coated tablets                      | Oral use |



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| Portugal | Servier Portugal -<br>Especialidades<br>Farmacêuticas, Lda.<br>Av. António Augusto de<br>Aguar, 128<br>1069-133 Lisboa<br>Portugal          | Vastarel                                               | 20 mg/ml | Oral solution           | Oral use |
| Portugal | Sanofi-Aventis - Produtos<br>Farmacêuticos, Lda.<br>Empreendimento Lagoas<br>Park, Edifício 7 - 3º Piso<br>2740-244 Porto Salvo<br>Portugal | Trimetazidina Zentiva                                  | 20 mg    | Coated tablets          | Oral use |
| Portugal | Labesfal - Laboratórios<br>Almiro, S.A. Zona<br>Industrial do Lagedo<br>3465-157 Santiago de<br>Besteiros<br>Portugal                       | Trimetazidina Labesfal 20<br>mg Comprimidos Revestidos | 20 mg    | Coated tablets          | Oral use |
| Portugal | Mylan, Lda.<br>Rua Doutor António<br>Loureiro Borges, Edifício<br>Arquiparque 1, R/C Esqº<br>1499-016 Algés<br>Portugal                     | Trimetazidina Mylan                                    | 20 mg    | Coated tablets          | Oral use |
| Portugal | Generis Farmacêutica, S.A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                          | Trimetazidina Generis 20<br>mg Comprimidos Revestidos  | 20 mg    | Coated tablets          | Oral use |
| Portugal | Servier Portugal -<br>Especialidades<br>Farmacêuticas, Lda.<br>Av. António Augusto de<br>Aguar, 128<br>1069-133 Lisboa<br>Portugal          | Vastarel LM                                            | 35 mg    | Modified-release tablet | Oral use |
| Portugal | Bluepharma Genéricos -<br>Comércio de Medicamentos,<br>S.A. São Martinho do<br>Bispo 3045-016<br>Coimbra Portugal                           | Trimetazidina Bluepharma<br>20 mg Comprimidos          | 20 mg    | Coated tablets          | Oral use |

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| Portugal | Vida - Produtos Farmacêuticos, S.A.<br>Rua da Estação, 42 - Vala do Carregado<br>2600-726 Castanheira do Ribatejo<br>Portugal                   | Trimetazidina Vida                                            | 20 mg | Coated tablets          | Oral use |
| Portugal | Helm Portugal, Lda.<br>Estrada Nacional n.º 10,<br>Km 140, 260<br>2695-066 Bobadela - Loures<br>Portugal                                        | Trimetazidina Baldacci 20 mg Comprimidos                      | 20 mg | Coated tablets          | Oral use |
| Portugal | Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda.<br>Lagoas Park, Edifício 5 A - Piso 2<br>2740-298 Porto Salvo<br>Portugal | Trimetazidina Mepha 20 mg Comprimidos Revestidos              | 20 mg | Coated tablets          | Oral use |
| Portugal | Jaba Recordati, S. A.<br>Lagoas Park, Edifício 5, Torre C, Piso 3 2740-298 Porto Salvo<br>Portugal                                              | Trimetazidina Jaba 20 mg Comprimidos revestidos               | 20 mg | Coated tablets          | Oral use |
| Portugal | Teva Pharma - Produtos Farmacêuticos, Lda<br>Lagoas Park, Edifício 1 - 3º<br>2740-264 Porto Salvo<br>Portugal                                   | Trimetazidina Teva                                            | 20 mg | Coated tablets          | Oral use |
| Portugal | Les Laboratoires Servier<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                                                    | Tacirel LM                                                    | 35 mg | Modified-release tablet | Oral use |
| Portugal | Cinfa Portugal, Lda.<br>Av. Tomás Ribeiro, 43 - Bloco 1, 4º B - Edifício Neopark<br>2790-221 Carnaxide<br>Portugal                              | Trimetazidina Cinfa 20 mg Comprimidos revestidos por película | 20 mg | Film-coated tablets     | Oral use |

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| Portugal | Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda.<br>Rua Quinta do Pinheiro - Edifício Tejo - 6º Piso<br>2790-143 Carnaxide Portugal | Trimetazidina Ratiopharm | 20 mg | Film-coated tablets       | Oral use |
| Portugal | Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda.<br>Rua Quinta do Pinheiro - Edifício Tejo - 6º Piso<br>2790-143 Carnaxide Portugal | Trimetazidina Ratiopharm | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Generis Farmacêutica, S.A.<br>Rua João de Deus, 19<br>2700-487 Amadora Portugal                                                                      | Trimetazidina Generis    | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Teva Pharma - Produtos Farmacêuticos, Lda<br>Lagoas Park, Edifício 1 - 3º<br>2740-264 Porto Salvo Portugal                                           | Trimetazidina Teva       | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo<br>3465-157 Santiago de Besteiros Portugal                                            | Trimetazidina Labesfal   | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Sandoz Farmacêutica, Lda.<br>Alameda da Beloura, Edifício 1, 2º - Escritório 15<br>2710-693 Sintra Portugal                                          | Trimetazidina Sandoz     | 35 mg | Prolonged-release tablets | Oral use |

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| Portugal | Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda.<br>Lagoas Park, Edifício 5 A - Piso 2 2740-298 Porto Salvo Portugal                                      | Trimetazidina Mepha LP      | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Bluepharma Genéricos - Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal                                                                          | Trimetazidina Bluepharma LP | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15 2710-693 Sintra Portugal                                                                          | Trimetazidina Itraxel       | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Pharmakern Portugal - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Edifício Atlas II, Av. José Gomes Ferreira, N.º 11 - 3º, Sala 31 - Miraflores 1495-139 Algés Portugal | Lupamadazine                | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Mylan, Lda. Rua Doutor António Loureiro Borges, Edifício Arquiparque 1, R/C Esqº 1499-016 Algés Portugal                                                                       | Trimetazidina Mylan         | 35 mg | Prolonged-release tablets | Oral use |
| Portugal | Sanofi-Aventis - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park, Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal                                                   | Zilutra                     | 35 mg | Prolonged-release tablets | Oral use |

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| Romania | MYLAN S.A.S.<br>117, Allée des Parcs<br>69800 Saint Priest<br>France                                          | Trimetazidina Mylan                                                       | 35 mg | Prolonged-release tablet | Oral use |
| Romania | S.C. TERAPIA S.A.<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                          | DILATAN MR 35 mg,<br>comprimate filmate cu<br>eliberare modificată, 35 mg | 35 mg | Prolonged-release tablet | Oral use |
| Romania | S.C. TERAPIA S.A.<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                          | DILATAN 20 mg,<br>comprimate filmate, 20 mg                               | 20mg  | Film-coated tablet       | Oral use |
| Romania | S.C. VIM SPECTRUM S.R.L.,<br>Șos. Sighișoarei nr. 409,<br>Sat Corunca, Com. Livezeni<br>Jud. Mureș<br>România | TRIMETAZIDIN VIM<br>SPECTRUM 20 mg, capsule                               | 20 mg | Capsule                  | Oral use |
| Romania | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                 | PREDUCTAL MR 35 mg,<br>comprimate filmate cu<br>eliberare modificată      | 35 mg | Modified-release tablet  | Oral use |
| Romania | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                 | PREDUCTAL 20 mg,<br>comprimate filmate                                    | 20 mg | Film-coated tablet       | Oral use |
| Romania | GEDEON RICHTER<br>ROMÂNIA S. A.<br>Str. Cuza - Vodă nr. 99 –<br>105<br>Târgu – Mureș<br>România               | MODUXIN MR 35 mg,<br>comprimate filmate cu<br>eliberare prelungită        | 35 mg | Prolonged-release tablet | Oral use |
| Romania | GEDEON RICHTER<br>ROMÂNIA S. A.<br>Str. Cuza - Vodă nr. 99 –<br>105<br>Târgu – Mureș<br>România               | MODUXIN 20 mg,<br>comprimate filmate                                      | 20 mg | Film-coated tablet       | Oral use |
| Romania | S.C. TERAPIA S.A.<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                          | TRIMETAZIDINA 20 mg,<br>drajeuri                                          | 20 mg | Coated tablet            | Oral use |

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| Romania            | LABORMED PHARMA S.A.<br>Bd. Theodor Pallady nr. 44B<br>sector 3, București<br>România         | TRIMETAZIDINĂ LPH 35mg,<br>comprimate filmate cu<br>eliberare modificată | 35 mg | Modified-release tablet                 | Oral use |
| Romania            | LABORMED PHARMA S.A.<br>Bd. Theodor Pallady nr. 44B<br>sector 3, București<br>România         | TRIMETAZIDINĂ LPH 20 mg,<br>comprimate filmate                           | 20 mg | Film-coated tablet                      | Oral use |
| Romania            | LABORMED PHARMA S.A.<br>Bd. Theodor Pallady nr. 44B<br>sector 3, București<br>România         | Oxcardin 20 mg,<br>comprimate filmate                                    | 20 mg | Film-coated tablet                      | Oral use |
| Romania            | LABORMED PHARMA S.A.<br>Bd. Theodor Pallady nr. 44B<br>sector 3, București<br>România         | Oxcardin MR 35mg,<br>comprimate filmate cu<br>eliberare modificată       | 35 mg | Modified-release tablet                 | Oral use |
| Romania            | GLENMARK<br>PHARMACEUTICALS s.r.o.<br>Hvezdova 1716/2b, Prague<br>4, 140 78<br>Czech Republic | APSTAR 35 mg comprimate<br>cu eliberare prelungită                       | 35 mg | Prolonged-release tablet                | Oral use |
| Romania            | S.C.SANDOZ S.R.L.<br>Str. Livezeni nr. 7A<br>540472 Târgu Mureș<br>România                    | TRIMELUZINE 35 mg<br>comprimate cu eliberare<br>prelungită               | 35 mg | Prolonged-release tablet                | Oral use |
| Slovak<br>Republic | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>89079 Ulm<br>Germany                                | Trimetazidin-ratiopharm 20<br>mg                                         | 20 mg | Film-coated tablet                      | Oral use |
| Slovak<br>Republic | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>89079 Ulm<br>Germany                                | Trimetazidin ratiopharm<br>retard 35 mg                                  | 35 mg | Modified-release film-<br>coated tablet | Oral use |
| Slovak<br>Republic | PRO.MED.CS PRAHA a.s.<br>Telčská 1<br>140 00 Praha<br>Czech Republic                          | Angitrim                                                                 | 20 mg | Film-coated tablet                      | Oral use |

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| Slovak Republic | EGIS Pharmaceuticals PLC<br>Keresztúri út 30-38,<br>1106 Budapest<br>Hungary                                                                          | Adexor                                                                             | 20 mg | Film-coated tablet                   | Oral use |
| Slovak Republic | Les Laboratoires Servier,<br>50, rue Carnot<br>92284 Suresnes cedex<br>France                                                                         | PREDUCTAL MR                                                                       | 35 mg | Modified-release film-coated tablet  | Oral use |
| Slovak Republic | Mylan S.A.S<br>117, Allée des Parcs<br>69800 Saint Priest<br>France                                                                                   | Trimetazidin Mylan 35 mg                                                           | 35 mg | Prolonged-release tablet             | Oral use |
| Slovak Republic | Deml Group s.r.o.<br>Jeneweinova 51a<br>617 00 Brno<br>Czech Republic                                                                                 | Trimetazidin - DemlGroup<br>PR 35 mg                                               | 35 mg | Prolonged-release film-coated tablet | Oral use |
| Slovak Republic | Actavis Group PTC ehf<br>Reykjavkurvegi 76-78<br>220 Hafnarfiroi<br>Iceland                                                                           | Vascotazin 35 mg                                                                   | 35 mg | Modified-release tablet              | Oral use |
| Slovak Republic | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvezdova 1716/2b 140 78<br>Praha 4<br>Czech Republic                                                            | Apstar 35 mg tablety s<br>predĺženým uvoľňovaním                                   | 35 mg | Prolonged-release tablet             | Oral use |
| Slovenia        | Servier Pharma d.o.o.<br>Pot k sejmiscu 33<br>SI-1231 Ljubljana Crnuce<br>Slovenia                                                                    | PREDUCTAL MR 35 mg<br>filmsko obložene tablete s<br>prirejenim sproščanjem         | 35 mg | Modified-release film-coated tablet  | Oral use |
| Slovenia        | Servier Pharma d.o.o.<br>Pot k sejmiscu 33<br>SI-1231 Ljubljana Crnuce<br>Slovenia                                                                    | TRIMETAZIDIN SERVIER 35<br>mg filmsko obložene tablete<br>s prirejenim sproščanjem | 35 mg | Modified-release film-coated tablet  | Oral use |
| Spain           | LABORATORIOS DAVUR,<br>S.L.<br>C/ Teide, 4- planta baja<br>Polígono Empresarial La<br>Marina<br>28703 San Sebastian de los<br>Reyes (MADRID)<br>Spain | TRIMETAZIDINA DAVUR 20<br>mg comprimidos recubiertos<br>EFG                        | 20 mg | Film-coated tablet                   | Oral use |

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| Spain | RIMAFAR, S.L.<br>Polígono Industrial Malpica<br>Calle C, N° 4<br>50016 ZARAGOZA<br>Spain                          | TRIMETAZIDINA RIMAFAR<br>20 mg comprimidos<br>recubiertos EFG                    | 20 mg    | Film-coated tablet | Oral use |
| Spain | RATIOPHARM ESPAÑA, S.A.<br>Avda. Burgos, 16 D-5ª<br>planta<br>28036 MADRID<br>Spain                               | TRIMETAZIDINA<br>RATIOPHARM 20 mg<br>comprimidos recubiertos con<br>película EFG | 20 mg    | Film-coated tablet | Oral use |
| Spain | DANVAL, S.A.<br>Avda. de los Madroños, 33<br>28043 Madrid<br>Spain                                                | IDAPTAN 20 mg<br>comprimidos recubiertos con<br>película                         | 20 mg    | Film-coated tablet | Oral use |
| Spain | DANVAL, S.A.<br>Avda. de los Madroños, 33<br>28043 Madrid<br>Spain                                                | IDAPTAN 20 mg/ml solución<br>oral                                                | 20 mg/ml | Oral solution      | Oral use |
| Spain | LABORATORIOS CINFA,<br>S.A.<br>C/ Olaz-Chipi, 10<br>Polígono Industrial Areta<br>31620 Huarte (PAMPLONA)<br>Spain | TRIMETAZIDINA CINFA 20<br>mg comprimidos recubiertos<br>con película EFG         | 20 mg    | Film-coated tablet | Oral use |
| Spain | PENSA PHARMA, S.A.U.<br>C/ Jorge Comín (Médico<br>Pediatra)<br>3-bajos<br>46015 Valencia<br>Spain                 | TRIMETAZIDINA PENSA 20<br>mg comprimidos recubiertos<br>con película EFG         | 20 mg    | Film-coated tablet | Oral use |