

## **Annex I**

**List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states**

| <b>Member State<br/>EU/EEA</b> | <b>Marketing authorisation holders<br/>company name, address</b>                | <b>(Invented) Names</b>                           | <b>Strengths</b> | <b>Pharmaceutical forms</b> | <b>Routes of administration</b> |
|--------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------|------------------|-----------------------------|---------------------------------|
| Bulgaria                       | Gedeon Richter Plc.,<br>Gyomroi ut 19/21,<br>H- 1103 Budapest,<br>Hungary       | Mydocalm                                          | 150 mg           | film-coated tablets         | oral use                        |
| Cyprus                         | M K STAVRINOS LTD,<br>P.O.BOX 21074,<br>1501 LEFKOSIA,<br>CYPRUS                | MYDOFLEX TABLET<br>150MG                          | 150MG            | Tablets                     | oral use                        |
| Czech Republic                 | Gedeon Richter Plc.,<br>Budapešť Gyömrői út 19-21<br>H-1103 Budapest<br>Hungary | MYDOCALM 150 MG                                   | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | Aliud Pharma GmbH<br>Gottlieb-Daimler-Str. 19<br>D-89150 Laichingen<br>Germany  | Tolperisonhydrochlorid AL<br>150 mg Filmtabletten | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | Aliud Pharma GmbH<br>Gottlieb-Daimler-Str. 19<br>D-89150 Laichingen<br>Germany  | Tolperisonhydrochlorid AL<br>50 mg Filmtabletten  | 50 mg            | film-coated tablet          | oral use                        |
| Germany                        | HEXAL AGIndustriestr. 25D-<br>83607 Holzkirchen<br>Germany                      | Tolperison HEXAL 50 mg                            | 50 mg            | film-coated tablet          | oral use                        |
| Germany                        | Mylan dura GmbH<br>Wittichstr. 6<br>D-64295 Darmstadt<br>Germany                | Tolperison-HCL dura 150<br>mg Filmtabletten       | 150 mg           | film-coated tablet          | oral use                        |

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|--------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------|------------------|-----------------------------|---------------------------------|
| Germany                        | Mylan dura GmbH<br>Wittichstr. 6<br>D-64295 Darmstadt<br>Germany                  | Tolperison-HCL dura 50 mg<br>Filmtabletten   | 50 mg            | film-coated tablet          | oral use                        |
| Germany                        | Orion Corporation<br>Orionintie 1<br>FIN-02200 ESPOO<br>Finland                   | Viveo                                        | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | PP Nature Balance Lizenz GmbH<br>Habichthorst 34-36<br>D-22459 Hamburg<br>Germany | Mydocalm                                     | 50 mg            | film-coated tablet          | oral use                        |
| Germany                        | SANOCHEMIA Pharmazeutika AG<br>Boltzmanngasse 9a-11<br>A-1090 Wien<br>Austria     | Tolpomusc 150 mg<br>Filmtabletten            | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | SANOCHEMIA Pharmazeutika AG<br>Boltzmanngasse 9a-11<br>A-1090 Wien<br>Austria     | Tolposan 150 mg<br>Filmtabletten             | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | Stadapharm GmbH<br>Stadastr. 2.18<br>D-61118 Bad-Vilbel<br>Germany                | Tolperison-HCL STADA<br>150 mg Filmtabletten | 150 mg           | film-coated tablet          | oral use                        |
| Germany                        | Stadapharm GmbH<br>Stadastr. 2.18<br>D-61118 Bad-Vilbel<br>Germany                | Tolperison-HCL STADA 50<br>mg Filmtabletten  | 50 mg            | film-coated tablet          | oral use                        |

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| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | MIDERIZONE 50 mg<br>filmtabletta  | 50 mg            | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | MIDERIZONE 150 mg<br>filmtabletta | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Flexirizon 50 mg filmtabletta     | 50 mg            | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Flexirizon 150 mg<br>filmtabletta | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Meditolp 50 mg filmtabletta       | 50 mg            | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Meditolp 150 mg filmtabletta      | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Merisone 50 mg filmtabletta       | 50 mg            | film-coated tablet          | oral use                        |

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| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Merisone 150 mg filmtabletta       | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myopax 50 mg filmtabletta          | 50 mg            | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myopax 150 mg filmtabletta         | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myoperizone 50 mg<br>filmtabletta  | 50 mg            | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myoperizone 150 mg<br>filmtabletta | 150 mg           | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myoson 50 mg filmtabletta          | 50mg             | film-coated tablet          | oral use                        |
| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Myoson 150 mg filmtabletta         | 150 mg           | film-coated tablet          | oral use                        |

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| Hungary                        | Meditop Gyógyszeripari Kft.<br>Ady E. u. 1.<br>2097, Pilisborosjenő<br>Hungary | Tolperisone Meditop 150 mg<br>filmtabletta           | 150 mg                   | film-coated tablet          | oral use                              |
| Hungary                        | Richter Gedeon nyrt.<br>Gyömrői út 19-21.<br>1103, Budapest<br>Hungary         | MYDETON 50 mg<br>filmtabletta                        | 50 mg                    | film-coated tablet          | oral use                              |
| Hungary                        | Richter Gedeon nyrt.<br>Gyömrői út 19-21.<br>1103, Budapest<br>Hungary         | MYDETON 150 mg<br>filmtabletta                       | 150 mg                   | film-coated tablet          | oral use                              |
| Hungary                        | Richter Gedeon nyrt.<br>Gyömrői út 19-21.<br>1103, Budapest<br>Hungary         | MYDETON injekció                                     | 100 mg + 2,5<br>mg / ml  | solution for<br>injection   | intravenous,<br>intarmuscular         |
| Latvia                         | Gedeon Richter Plc.,<br>Gyömrői út 19 – 21,<br>1103 Budapest,<br>Hungary       | Mydocalm 50 mg apvalkotās<br>tabletes                | 50 mg                    | film-coated tablet          | oral use                              |
| Latvia                         | Gedeon Richter Plc.,<br>Gyömrői út 19 – 21,<br>1103 Budapest,<br>Hungary       | Mydocalm 150 mg<br>apvalkotās tabletes               | 150 mg                   | film-coated tablet          | oral use                              |
| Latvia                         | Gedeon Richter Plc.,<br>Gyömrői út 19 – 21,<br>1103 Budapest,<br>Hungary       | Mydocalm 100 mg/ml + 2,5<br>mg/ml šķīdums injekcijām | 100 mg/ml + 2,5<br>mg/ml | Solution for<br>injection   | intramuscular use,<br>intravenous use |

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|--------------------------------|---------------------------------------------------------------------------|-------------------------|-------------------------|-----------------------------|---------------------------------|
| Lithuania                      | Gedeon Richter Plc.,<br>Gyomroi ut 19-21,<br>Budapest, H- 1103<br>Hungary | MYDOCALM                | 150mg                   | film-coated tablet          | oral use                        |
| Lithuania                      | Gedeon Richter Plc.,<br>Gyomroi ut 19-21,<br>Budapest, H- 1103<br>Hungary | MYDOCALM                | 50mg                    | film-coated tablet          | oral use                        |
| Lithuania                      | Gedeon Richter Plc.,<br>Gyomroi ut 19-21,<br>Budapest, H- 1103<br>Hungary | MYDOCALM                | 100mg/2,5<br>mg/ml      | Solution for<br>injection   | Intramuscular/intravenous use   |
| Poland                         | Gedeon Richter Plc.<br>Budapest, Gyomroi 19-21<br>1103<br>Hungary         | Mydocalm                | 50 mg                   | film- coated tablet         | oral use                        |
| Poland                         | Gedeon Richter Plc.<br>Budapest, Gyomroi 19-21<br>1103<br>Hungary         | Mydocalm                | (100 mg + 2,5<br>mg)/ml | solution for<br>injection   | Intramuscular/intravenous use   |
| Poland                         | Gedeon Richter Plc.<br>Budapest, Gyomroi 19-21<br>1103<br>Hungary         | Mydocalm forte          | 150 mg                  | film-coated tablet          | oral use                        |
| Poland                         | ICN Polfa Rzeszów S.A.<br>Rzeszów,<br>Przemysłowa 2<br>35-959<br>Poland   | Tolperis VP             | 50 mg                   | film-coated tablet          | oral use                        |

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| Romania                        | GEDEON RICHTER ROMÂNIA S.A.<br>Str. Cuza-Vodă nr.<br>99-105, Târgu Mureș,<br>România | MYDOCALM                | 100mg/ml         | solution for injection      | Intramuscular/intravenous use   |
| Romania                        | GEDEON RICHTER ROMÂNIA S.A.<br>Str. Cuza-Vodă nr.<br>99-105, Târgu Mureș,<br>România | MYDOCALM 50 mg          | 50 mg            | film-coated tablet          | oral use                        |
| Romania                        | GEDEON RICHTER ROMÂNIA S.A.<br>Str. Cuza-Vodă nr.<br>99-105, Târgu Mureș,<br>România | MYDOCALM 150 mg         | 150 mg           | film-coated tablet          | oral use                        |
| Romania                        | S.C. TERAPIA S.A.<br>Str. Fabricii nr. 124,<br>Cluj Napoca,<br>România               | TOLPERISON 50 mg        | 50 mg            | coated tablet               | oral use                        |
| Slovak Republic                | Gedeon Richter Plc.<br>Gyömrői út 19-21.<br>H-1103 Budapest<br>Hungary               | MYDOCALM 150 mg         | 150 mg           | film-coated tablet          | oral use                        |
| Slovak Republic                | Gedeon Richter Plc.<br>Gyömrői út 19-21.<br>H-1103 Budapest<br>Hungary               | MYDOCALM                | 100mg/1ml        | Solution for injection      | Intramuscular/intravenous use   |