

5 December 2019  
EMA/48333/2014 corr. 2\*  
Inspections, Human Medicines Pharmacovigilance & Committees

List of thiolcolchicoside-containing medicinal products in the EU

| Name of the product                                      | Marketing Authorisation Holder               | Country where product is authorised |
|--|--|-------------------------------------|
| Muscorig INJ   | Sanofi-aventis, s.r.o.                       | Czech Republic                      |
| Muscorig CPS   | Sanofi-aventis, s.r.o.                       | Czech Republic                      |
| Colthiozid 4 mg/2 ml, solution injectable                | Laboratoires Pharym II                       | France                              |
| Coltramyl 4 mg, comprimé                                 | Sanofi Aventis France                        | France                              |
| Coltramyl 4 mg/2 ml, solution injectable IM en ampoule   | Sanofi Aventis France                        | France                              |
| Miorel 4 mg, gélule                                      | Daiichi Sankyo France SAS                    | France                              |
| Miorel 4 mg/2 ml, solution injectable (IM) en ampoule    | Daiichi Sankyo France SAS                    | France                              |
| Myoplege 4 mg, gélule                                    | Laboratoires Genevrier S.A.                  | France                              |
| Thiolcolchicoside Actavis 4 mg, comprimé                 | Actavis Group PTC ehf                        | France                              |
| Thiolcolchicoside Almus 4 mg, comprimé                   | Bioqaran                                     | France                              |
| Thiolcolchicoside Alter 4 mg, comprimé                   | Alter  | France                              |
| Thiolcolchicoside Arrow 4 mg, comprimé                   | Arrow Generiques                             | France                              |
| Thiolcolchicoside Biogaran 4 mg, comprimé                | Biogaran                                     | France                              |
| Thiolcolchicoside Cristers 4 mg, comprimé                | Cristers                                     | France                              |
| Thiolcolchicoside EG 4 mg, comprimé sécable              | Eq Labo - Laboratoires Eurogenerics          | France                              |
| Thiolcolchicoside Mylan 4 mg, comprimé                   | Mylan SAS                                    | France                              |
| Thiolcolchicoside Ratiopharm 4 mg, comprimé sécable      | Ratiopharm (Germany)                         | France                              |
| Thiolcolchicoside Sandoz 4 mg, comprimé                  | Sandoz                                       | France                              |
| Thiolcolchicoside Teva 4 mg, comprimé                    | Teva Sante                                   | France                              |
| Thiolcolchicoside Zentiva 4 mg, comprimé                 | Sanofi Aventis France                        | France                              |
| Musco-Ril 4 mg capsule                                   | Sanofi-Aventis AEBE                          | Greece                              |
| Musco-Ril 4 mg/2 ml solution for injection               | Sanofi-Aventis AEBE                          | Greece                              |
| Relief 4 mg capsule                                      | Iasis Pharmaceuticals                        | Greece                              |
| Relief 4 mg/2 ml solution for injection                  | Iasis Pharmaceuticals                        | Greece                              |
| Muscorig 4 mg capsule, hard                              | Sanofi - Aventis                             | Hungary                             |
| Muscorig 4 mg solution for injection                     | Sanofi - Aventis                             | Hungary                             |
| Muscorig 4 mg/2 ml solution for injection                | Sanofi Aventis S.P.A.                        | Italy                               |
| Muscorig 4 mg capsule, hard                              | Sanofi Aventis S.P.A.                        | Italy                               |
| Muscorig 8 mg capsule, hard                              | Sanofi Aventis S.P.A.                        | Italy                               |
| Muscorig 8 mg orodispersible tablet                      | Sanofi Aventis S.P.A.                        | Italy                               |
| Tiocolchicoside Zentiva 4 mg capsule, hard               | Zentiva Italia S.R.L.                        | Italy                               |
| Tiocolchicoside Zentiva 4 mg/2 ml solution for injection | Zentiva Italia S.R.L.                        | Italy                               |
| Tioside 4 mg capsule, hard                               | Farmaceutici Caber S.P.A.                    | Italy                               |
| Tioside 4 mg/2 ml solution for injection                 | Farmaceutici Caber S.P.A.                    | Italy                               |
| Miotens  | Dompe S.P.A.                                 | Italy                               |
| Tiocolchicoside  | Doc Generici S.R.L.                          | Italy                               |
| Sciomir  | Laboratorio Farmaceutico C.T. S.R.L.         | Italy                               |
| Muscoflex  | Epifarma S.R.L.                              | Italy                               |
| Tiocolchicoside Union Health                             | Union Health S.R.L.                          | Italy                               |
| Tiocolchicoside Mylan Generics                           | Mylan S.P.A.                                 | Italy                               |
| Decontril  | Crinos S.P.A.                                | Italy                               |
| Strialisin   | MDM S.P.A.                                   | Italy                               |
| Tiocolchicoside EG                                       | EG S.P.A.                                    | Italy                               |
| Tiocolchicoside Gerned                                   | Gerned Pharma S.P.A.                         | Italy                               |
| Tiocolchicoside  | Sandoz S.P.A.                                | Italy                               |
| Tiocolchicoside Anqenerico                               | Anqenerico S.P.A.                            | Italy                               |
| Teraside   | Wellington Street Development Pharma Limited | Italy                               |
| Miorexil   | SPA - Societa' Prodotti                      | Italy                               |
| Coltramyl  | Sanofi-Aventis Malta Ltd                     | Malta                               |
| Adalgur N  | Angelini Farmacêutica, Lda.                  | Portugal                            |
| Tiocolchicosido Generis                                  | Generis Farmacêutica, S.A.                   | Portugal                            |
| <b>Tiocolchicosido Arrowblue**</b>                       | <b>Generis Farmacêutica, S.A.</b>            | <b>Portugal</b>                     |
| Relmus 8 mg capsule                                      | Sanofi - Produtos Farmacêuticos, Lda.        | Portugal                            |

| Name of the product                        | Marketing Authorisation Holder         | Country where product is authorised |
|--|--|-------------------------------------|
| Relmus 4 mg/ 2ml solution for injection    | Sanofi - Produtos Farmacêuticos, Lda.  | Portugal                            |
| Relmus 4 mg capsule                        | Sanofi - Produtos Farmacêuticos, Lda.  | Portugal                            |
| Relmus 8 mg orodispersible tablet          | Sanofi - Produtos Farmacêuticos, Lda.  | Portugal                            |
| Coltramyl 4 mg tablet                      | Koranqi - Produtos Farmacêuticos, Lda. | Portugal                            |
| Coltramyl 4 mg/2 ml solution for injection | Koranqi - Produtos Farmacêuticos, Lda. | Portugal                            |
| Adalcur Comprimidos                        | Teofarma, S.R.L.                       | Spain                               |

\* This annex was previously amended on 28 October 2015.

\*\* The medicinal product Tiocholquicosido Arrowblue has been removed from this annex as its marketing authorisation was withdrawn in Portugal.