



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2020
EMA/230507/2020
Human Medicines Division

List of nationally authorised medicinal products

Active substance: thiocolcicoside

Procedure no.: EMEA/H/N/PSR/J/0023

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Annex I – LABORATOIRES ALTER

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside Alter 4 mg, comprimé	Not Applicable	NL 27344	Laboratoires ALTER	France	Not applicable

Annex I – ANGELINI FARMACÊUTICA, Lda

Specific Information for PASS107 Submissions

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	Legal Basis
Adalgur N	Not applicable	5663380, 5663281	Angelini Farmacêutica, Lda.	Portugal	Not applicable

Annex I – ARISTO PHARMA GmbH

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside Aristo	Not applicable	035826015	Aristo Pharma GmbH	Italy	Not applicable

Annex I – ARROW GÉNÉRIQUES

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside Arrow 4 mg, comprimé	Not applicable	NL 27343	Arrow Génériques	France	Not applicable

Annex I - BIOGARAN

Specific Information for PASS107 Submissions

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	Not applicable
Thiocolchicoside Biogaran 4 mg, comprimé	Not applicable	NL 27342	BIOGARAN	France	Not applicable
Thiocolchicoside Almus 4 mg, comprimé	Not applicable	NL 27974	BIOGARAN	France	Not applicable

Annex I – CRISTERS

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside Cristers 4mg, comprimé	Not applicable	NL 27973	Cristers	France	Not applicable

Annex I – DAIICHI SANKYO FRANCE

Specific Information for PASS107 Submissions

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	Legal Basis
Miorel 4 mg/2 ml, injectable solution (IM) in ampoule	Not applicable	NL 16704	Daiichi Sankyo France	France	Not applicable
Miorel 4 mg, capsule	Not applicable	NL 16703	Daiichi Sankyo France	France	Not applicable

Annex I – DOC GENERICI S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside Doc Generici	Not applicable	034895	Doc Generici S.r.l.	Italy	Not applicable

Annex I – DOMPÉ FARMACEUTICI S.p.A.

Specific Information for PASS107 Submissions

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	Legal Basis
Miotens 4 mg/2 ml soluzione iniettabile i.m.	Not applicable	034424010	Dompé farmaceutici S.p.A.	Italy	Not applicable

Annex I – EG LABO – LABORATOIRES EUROGENERICS

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside EG 4 mg comprimé sécable	Not applicable	NL26739	EG labo	France	Not applicable

Annex I – EG S.p.A.

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside EG 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035328018	EG SpA Italy	Italy	Not applicable

Annex I – EPIFARMA S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Muscoflex	Not applicable	034914010	Epifarma S.r.l.	Italy	Not applicable

Annex I – GENERIS FARMACÊUTICA S.A.

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolquicosido Generis 4 mg Comprimido	Not applicable	05/H/0304/001	Generis Farmacêutica S.A.	Portugal	Not applicable
Tiocolquicosido Arrowblue 4 mg Comprimido	Not applicable	05/H/0305/001	Generis Farmacêutica S.A.	Portugal	Not applicable

Annex I – I.B.N. Savio S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Tioside, 4mg/2ml soluzione iniettabile per uso intramuscolare	Not applicable	033982012	I.B.N. Savio S.r.l.	Italy	Not applicable
Tioside, 4 mg capsule rigide	Not applicable	033982024	I.B.N. Savio S.r.l.	Italy	Not applicable

Annex I – KORANGI PRODUTOS FARMACÊUTICOS Lda

Specific Information for PASS107 Submissions

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	Legal Basis
ColtramyI 4 mg Comprimidos	Not applicable	2200996 5606272	Korangi Produtos Farmacêuticos Lda	Portugal	Not applicable
ColtramyI 4 mg/2 ml Solução injetável	Not applicable	2201184 5615901	Korangi Produtos Farmacêuticos Lda	Portugal	Not applicable

Annex I – LABORATORIO FARMACEUTICO CT S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Sciomir 2mg/ml injectable solution	Not applicable	034898027	Laboratorio Farmaceutico CT Srl	Italy	Not applicable

Annex I – MDM S.p.A.

Specific Information for PASS107 Submissions

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	Legal Basis
Strialisin – 4 mg/2 ml soluzione iniettabile	Not applicable	035314	MDM S.p.A.	Italy	Not applicable

Annex I – MYLAN

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside Mylan Generics 4 mg / 2 ml Injection (Solution in Ampoules)	Not applicable	035077015	Mylan SpA	Italy	Not applicable
Thiocolchicoside Mylan 4 mg, comprimé	Not applicable	NL 26056	Mylan SAS	France	Not applicable

Annex I – SANDOZ SAS

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside Sandoz 4 mg, comprimé	Not applicable	NL 26704	Sandoz SAS	France	Not applicable

Annex I – SANDOZ S.p.A.

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside sandoz	Not applicable	035758 010	Sandoz S.p.A	Italy	Not applicable

Annex I – SANOFI-AVENTIS GROUPE

Specific Information for PASS107 Submissions

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	Legal Basis
Coltramyl 4 mg/2 ml, solution for injection	Not applicable	V 00537	Sanofi-aventis France	France	Not applicable
Muscoril cps	Not applicable	63/168/98-C,	sanofi-aventis, s.r.o. Czech Republic	Czech Republic	Not applicable
Muscoril inj.	Not applicable	63/167/98-C	sanofi-aventis, s.r.o. Czech Republic	Czech Republic	Not applicable
Musco-ril caps. 4mg/cap	Not applicable	45294/21-09-2009	sanofi-aventis AEBE	Greece	Not applicable
Musco-ril inj.sol. 4mg/2ml amp	Not applicable	45292/21-09-2009	sanofi-aventis AEBE	Greece	Not applicable
MuscoriL 4 mg capsule rigide	Not applicable	015896107	Sanofi S.p.A.	Italy	Not applicable
Muscoril 8 mg capsule rigide	Not applicable	015896119	Sanofi S.p.A.	Italy	Not applicable
Muscoril 8 mg compresse orodispersibili	Not applicable	015896121	Sanofi S.p.A.	Italy	Not applicable
Muscoril 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	015896018	Sanofi S.p.A.	Italy	Not applicable
MuscoriL 4 mg hard capsule	Not applicable	AA 082/09801	Sanofi Malta Ltd	Malta	Not applicable
Relmus Capsules 4 mg	Not applicable	(20) – 8181503 (30) – 5594452	Sanofi – Produtos Farmacêuticos, Lda.	Portugal	Not applicable

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	Legal Basis
Relmus Capsules 8 mg	Not applicable	(10) - 5605837 (10) - 5605829 (14) - 5593108 (14) - 5593074	Sanofi - Produtos Farmacêuticos, Lda.	Portugal	Not applicable
Relmus Orodispersible tablet 8 mg	Not applicable	(10) - 5605845 (14) - 5593066	Sanofi - Produtos Farmacêuticos, Lda.	Portugal	Not applicable
Relmus Solution for injection 4 mg/2 ml	Not applicable	(6) - 8181602 (10) - 5605852	Sanofi - Produtos Farmacêuticos, Lda.	Portugal	Not applicable

Annex I – S.F. GROUP S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Decontril 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035078017	S.F. Group S.r.l.	Italy	Not applicable
Teraside	Not applicable	035966011	S.F. Group S.r.l.	Italy	Not applicable

Annex I – SPA-Società Prodotti Antibiotici S.p.A.

Specific Information for PASS107 Submissions

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	Legal Basis	Customer Account Number (only for PASS107)	Purchase Order Number (only for PASS 107)
Miorexil 4 mg solution for injection for intramuscular use	Not applicable	036320012	SPA-Società Prodotti Antibiotici S.p.A.	Italy	Not applicable	603962	Not applicable

Annex I – TEOFARMA S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Adalgur 500 mg / 2 mg, comprimidos	Not applicable	46534	Teofarma S.r.l.	Spain	Not applicable

Annex I – UNION HEALTH S.r.l.

Specific Information for PASS107 Submissions

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	Legal Basis
Tiocolchicoside Union Health 4 mg/2 ml soluzione iniettabile per uso intramuscolare	Not applicable	035073016	Union Health Srl	Italy	Not applicable

Annex I – ZENTIVA

Specific Information for PASS107 Submissions

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	Legal Basis
Thiocolchicoside Zentiva 4mg, comprimé	Not applicable	NL 24233	Zentiva France	France	Not applicable
Tiocolchicoside Zentiva 4 mg capsule rigide	Not applicable	033009034	Zentiva Italia S.r.l.	Italy	Not applicable
Tiocolchicoside Zentiva 4 mg/2ml soluzione iniettabile per uso intramuscolare	Not applicable	033009022	Zentiva Italia S.r.l.	Italy	Not applicable