



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2020
EMA/128326/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tolperisone

Procedure no.: PSUSA/00002991/201906



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Tolperison-HCl Sanochemia 150 mg Filmdabletten Tolperisonhydrochlorid	not available	63957.00.00	SANOCHEMIA PHARMAZEUTIKA AG	DE
Meditolp 150 mg filmdabletten	not available	OGYI-T-21989/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletten	not available	OGYI-T-22019/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletten	not available	OGYI-T-22019/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmdabletten	not available	OGYI-T-21990/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletten	not available	OGYI-T-22019/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletten	not available	OGYI-T-22019/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletten	not available	OGYI-T-22019/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletten	not available	OGYI-T-22019/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletten	not available	OGYI-T-22019/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletten	not available	OGYI-T-22019/08	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmdabletten	not available	OGYI-T-21990/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU

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Myoperizone 50 mg filmtabletta	not available	OGYI-T-21990/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmtabletta	not available	OGYI-T-21990/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
MYDOCALM 150 mg filmom obalené tablety	not available	63/0048/77-S	GEDEON RICHTER PLC.	SK
Tolperison NeuroPharma, 50 mg, tabletki powlekane	PL/H/0536/001	24063	NEURAXPHARM ARZNEIMITTEL GMBH	PL
Tolperison NeuroPharma, 150 mg, tabletki powlekane	PL/H/0536/002	24064	NEURAXPHARM ARZNEIMITTEL GMBH	PL
MYDOCALM 50 mg comprimate filmate	not available	7642/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO
MYDOCALM 150 mg comprimate filmate	not available	7643/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO
MYDOCALM 150 mg comprimate filmate	not available	7643/2015/02	GEDEON RICHTER ROMÂNIA S.A.	RO
Mydocalm 150 mg potahované tablety	not available	63/092/00-C	GEDEON RICHTER PLC.	CZ
Tolperison-HCl dura 150 mg Filmtabletten	DE/H/2659/002	74244.00.00	MYLAN DURA GMBH	DE
Tolperison-HCl dura 50 mg Filmtabletten	DE/H/2659/001	74243.00.00	MYLAN DURA GMBH	DE

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MYDOCALM 150 mg film-coated tablets	not available	9900289	GEDEON RICHTER PLC.	BG
Mydoflex® tablets	not available	16780	M.K. STAVRINOS LTD	CY
Tolperis VP, 50 mg, tabletki powlekane	not available	9597	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
MYDOCALM 50 mg plėvele dengtos tabletės	not available	LT/1/94/0951/001	GEDEON RICHTER PLC.	LT
MYDOCALM 150 mg plėvele dengtos tabletės	not available	LT/1/94/0951/002	GEDEON RICHTER PLC.	LT
Mydocalm 150 mg apvalkotās tabletes	not available	97-0349	GEDEON RICHTER PLC.	LV
Mydocalm 50 mg apvalkotās tabletes	not available	95-0152	GEDEON RICHTER PLC.	LV
Tolperisonhydrochlorid AL 50 mg Filmtabletten	DE/H/3785/001	74324.00.00	ALIUD PHARMA GMBH	DE
Tolperisonhydrochlorid AL 150 mg Filmtabletten	DE/H/3785/002	74325.00.00	ALIUD PHARMA GMBH	DE
Mydocalm, 50 mg, tabletki powlekane	not available	R/2279	GEDEON RICHTER PLC.	PL
Mydocalm Forte, 150 mg, tabletki powlekane	not available	R/2280	GEDEON RICHTER PLC.	PL
Tolperison-HCl neuraxpharm 50 mg Filmtabletten	DE/H/4678/001	92478.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE

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Tolperison-HCl neuraxpharm 150 mg Filmdabletten	DE/H/4678/002	92479.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Tolperison - 1 A Pharma 50 mg Filmdabletten	not available	61746.00.00	1 A PHARMA GMBH	DE
Mydocalm® 50 mg, Filmdabletten	not available	3001940.00.00	STRATHMANN GMBH & CO. KG	DE
Tolperison-HCl STADA® 50 mg Filmdabletten	DE/H/3784/001	74322.00.00	STADAPHARM GMBH	DE
Tolperison-HCl STADA® 150 mg Filmdabletten	DE/H/3784/002	74323.00.00	STADAPHARM GMBH	DE
Mydeton 150 mg filmdabletten	not available	OGYI-T-3282/03	GEDEON RICHTER PLC.	HU
Mydeton 50 mg filmdabletten	not available	OGYI-T-3282/02	GEDEON RICHTER PLC.	HU
Tolpermyo 50 mg filmomhulde tableten	HU/H/0377/001	RVG 115493	WILL PHARMA B.V.	NL
Tolpermyo 150 mg filmomhulde tableten	HU/H/0377/002	RVG 115494	WILL PHARMA B.V.	NL
Tolpermyo 50 mg filmomhulde tableten	HU/H/0519/001	BE534524	WILL-PHARMA S.A.	BE
Tolpermyo 50 mg comprimés pelliculés	HU/H/0519/001	BE534524	WILL-PHARMA S.A.	BE
Tolpermyo 50 mg Filmdabletten	HU/H/0519/001	BE534524	WILL-PHARMA S.A.	BE
Tolpermyo 150 mg filmomhulde tableten	HU/H/0519/002	BE534533	WILL-PHARMA S.A.	BE

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Tolpermyo 150 mg comprimés pelliculés	HU/H/0519/002	BE534533	WILL-PHARMA S.A.	BE
Tolpermyo 150 mg Filmtabletten	HU/H/0519/002	BE534533	WILL-PHARMA S.A.	BE