



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2025
EMA/29577/2025
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tolperisone

Procedure no.: PSUSA/00002991/202406



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
Flexirizon 150 mg filmdabletta	not available	OGYI-T-22019/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletta	not available	OGYI-T-22019/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletta	not available	OGYI-T-22019/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 150 mg filmdabletta	not available	OGYI-T-22019/08	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletta	not available	OGYI-T-22019/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletta	not available	OGYI-T-22019/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletta	not available	OGYI-T-22019/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Flexirizon 50 mg filmdabletta	not available	OGYI-T-22019/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 150 mg filmdabletta	not available	OGYI-T-21989/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU

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Meditolp 150 mg filmdabletta	not available	OGYI-T-21989/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 150 mg filmdabletta	not available	OGYI-T-21989/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 150 mg filmdabletta	not available	OGYI-T-21989/08	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 50 mg filmdabletta	not available	OGYI-T-21989/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 50 mg filmdabletta	not available	OGYI-T-21989/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 50 mg filmdabletta	not available	OGYI-T- 21989/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Meditolp 50 mg filmdabletta	not available	OGYI-T-21989/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 150 mg filmdabletta	not available	OGYI-T- 21220/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 150 mg filmdabletta	not available	OGYI-T-21220/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU

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Miderizone 150 mg filmdabletta	not available	OGYI-T-21220/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 150 mg filmdabletta	not available	OGYI-T-21220/08	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 50 mg filmdabletta	not available	OGYI-T- 21220/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 50 mg filmdabletta	not available	OGYI-T-21220/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 50 mg filmdabletta	not available	OGYI-T-21220/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Miderizone 50 mg filmdabletta	not available	OGYI-T-21220/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myderison 150 mg comprimate filmdate	not available	11571/2019/01	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 150 mg comprimate filmdate	not available	11571/2019/02	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 150 mg comprimate filmdate	not available	11571/2019/03	MEDITOP PHARMACEUTICAL CO. LTD.	RO

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
Myderison 150 mg comprimate filmate	not available	11571/2019/04	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 50 mg comprimate filmate	not available	11570/2019/01	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 50 mg comprimate filmate	not available	11570/2019/02	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 50 mg comprimate filmate	not available	11570/2019/03	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Myderison 50 mg comprimate filmate	not available	11570/2019/04	MEDITOP PHARMACEUTICAL CO. LTD.	RO
Mydeton 150 mg filmdtableta	not available	OGYI-T-3282/03	GEDEON RICHTER PLC.	HU
Mydeton 50 mg filmdtableta	not available	OGYI-T-3282/02	GEDEON RICHTER PLC.	HU
Mydocalm 150 mg apvalkotās tabletes	not available	97-0349	GEDEON RICHTER PLC.	LV
MYDOCALM 150 mg comprimate filmate	not available	7643/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO

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
MYDOCALM 150 mg comprimate filmate	not available	7643/2015/02	GEDEON RICHTER ROMÂNIA S.A.	RO
MYDOCALM 150 mg filmom obalené tablety	not available	63/0048/77-S	GEDEON RICHTER PLC.	SK
MYDOCALM 150 mg plevėle dengtos tabletės	not available	LT/1/94/0951/002	GEDEON RICHTER PLC.	LT
Mydocalm 150 mg potahované tablety	not available	63/092/00-C	GEDEON RICHTER PLC.	CZ
MYDOCALM 50 mg comprimate filmate	not available	7642/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO
Mydocalm Forte 150 mg tabletki powlekane	not available	R/2280	GEDEON RICHTER PLC.	PL
Mydocalm Forte 150 mg tabletki powlekane	not available	R/2280	GEDEON RICHTER PLC.	PL
Mydocalm, 50 mg, tabletki powlekane	not available	R/2279	GEDEON RICHTER PLC.	PL
Mydocalm, 50 mg, tabletki powlekane	not available	R/2279	GEDEON RICHTER PLC.	PL

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
Mydocalm®Filmtabletten	not available	3001940.00.00	STRATHMANN GMBH & CO. KG	DE
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/06	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/07	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/08	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/09	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 150 mg filmtabletta	not available	OGYI-T-21990/10	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmtabletta	not available	OGYI-T-21990/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmtabletta	not available	OGYI-T-21990/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmtabletta	not available	OGYI-T-21990/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU

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
Myoperizone 50 mg filmdabletta	not available	OGYI-T-21990/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Myoperizone 50 mg filmdabletta	not available	OGYI-T-21990/05	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Tolperis VP, 50 mg, tabletki powlekane	not available	9597	BAUSCH HEALTH IRELAND LIMITED	PL
Tolperison - 1 A Pharma 50 mg Filmdabletten	not available	61746.00.00	1 A PHARMA GMBH	DE
Tolperisone MEDITOP 150 mg filmdabletta	not available	OGYI-T-21988/01	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Tolperisone MEDITOP150 mg filmdabletta	not available	OGYI-T-21988/02	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Tolperisone MEDITOP150 mg filmdabletta	not available	OGYI-T-21988/03	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Tolperisone MEDITOP150 mg filmdabletta	not available	OGYI-T-21988/04	MEDITOP PHARMACEUTICAL CO. LTD.	HU
Tolperison-HCl dura 150 mg Filmdabletten Wirkstoff: Tolperisonhydrochlorid	DE/H/2659/002	74244.00.00	MYLAN GERMANY GMBH	DE

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Tolperison-HCl dura 150 mg Filmtabletten Wirkstoff: Tolperisonhydrochlorid	DE/H/2659/002	74244.00.00	MYLAN GERMANY GMBH	DE
Tolperison-HCl dura 50 mg Filmtabletten	DE/H/2659/001	74243.00.00	MYLAN GERMANY GMBH	DE
Tolperison-HCl dura 50 mg Filmtabletten	DE/H/2659/001	74243.00.00	MYLAN GERMANY GMBH	DE
Tolperison-HCl STADA® 150 mg Filmtabletten	DE/H/3784/002	74323.00.00	STADAPHARM GMBH	DE
Tolperison-HCl STADA® 50 mg Filmtabletten	DE/H/3784/001	74322.00.00	STADAPHARM GMBH	DE
Tolperisonhydrochlorid AL 150 mg Filmtabletten	DE/H/3785/002	74325.00.00	ALIUD PHARMA GMBH	DE
Tolperisonhydrochlorid AL 50 mg Filmtabletten	DE/H/3785/001	74324.00.00	ALIUD PHARMA GMBH	DE
Tolpermyo 150 mg filmomhulde tabletten	NL/H/4113/002	RVG 115494	WILL PHARMA B.V.	NL
Tolpermyo 50 mg filmomhulde tabletten	NL/H/4113/001	RVG 115493	WILL PHARMA B.V.	NL

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Мидокалм 150 mg филмирани таблетки	not available	9900289	GEDEON RICHTER PLC.	BG