



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2020
EMA/277590/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: itopride

Procedure no.: PSUSA/00010606/201906

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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
Ganaton 50 mg filmom obalené tablety	not available	49/0139/00-S	MYLAN IRE HEALTHCARE LIMITED	SK
Zirid, 50 mg, tabletki powlekane	CZ/H/0289/001	17590	ZENTIVA, K.S.	PL
Zirid 50 mg plévele dengtos tabletès	CZ/H/0289/001	LT/1/10/2209/001	ZENTIVA, K.S.	LT
Zirid 50 mg plévele dengtos tabletès	CZ/H/0289/001	LT/1/10/2209/002	ZENTIVA, K.S.	LT
Зирид 50 mg филмирани таблетки	CZ/H/0289/001	20110023	ZENTIVA, K.S.	BG
Kinito 50 mg, potahované tablety	CZ/H/0289/001	49/819/10-C	ZENTIVA, K.S.	CZ
Kinito 50 mg, filmom obalené tablety	CZ/H/0289/001	49/0792/10-S	ZENTIVA, A.S.	SK
Itoprid Xantis 50 mg tablety	SK/H/0159/001	49/252/16-C	XANTIS PHARMA LIMITED	CZ
Itoprid Xantis 50 mg tablety	SK/H/0159/001	49/0272/16-S	XANTIS PHARMA LIMITED	SK
ASKETON 50 mg potahované tablety	EE/H/0207/001	49/284/16-C	MEDOCHEMIE LTD.	CZ
Astipal, 50 mg õhukese polõmeerikattega tabletid	EE/H/0207/001	912816	MEDOCHEMIE LTD.	EE
ASKETON 50 mg filmom obalené tablety	EE/H/0207/001	49/0337/16-S	MEDOCHEMIE LTD.	SK
МЕДОПРИД 50 mg филмирани таблетки	EE/H/0207/001	20160236	MEDOCHEMIE LTD.	BG
ASTIPAL 50 mg plévele dengtos tabletès	EE/H/0207/001	LT/1/16/3933/001	MEDOCHEMIE LTD.	LT
ASTIPAL 50 mg plévele dengtos tabletès	EE/H/0207/001	LT/1/16/3933/002	MEDOCHEMIE LTD.	LT

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
ASTIPAL 50 mg plèvele dengtos tabletès	EE/H/0207/001	LT/1/16/3933/003	MEDOCHEMIE LTD.	LT
ASTIPAL 50 mg plèvele dengtos tabletès	EE/H/0207/001	LT/1/16/3933/004	MEDOCHEMIE LTD.	LT
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/01	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/02	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/03	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/04	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/05	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/06	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/07	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	9342/2016/08	MEDOCHEMIE LTD.	RO
Toprisan, 50 mg film-coated tablets	EE/H/0207/001	MA032/09501	MEDOCHEMIE LTD.	MT
Toprisan 50 mg, επικαλυμμένα με λεπτό υμένιο δισκία	EE/H/0207/001	022533	MEDOCHEMIE LTD.	CY
Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/01	SUPREMEX KFT.	HU
Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/02	SUPREMEX KFT.	HU

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Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/03	SUPREMEX KFT.	HU
Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/04	SUPREMEX KFT.	HU
Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/05	SUPREMEX KFT.	HU
Itopride Supremex 50 mg filmtabletta	not available	OGYI-T-23235/06	SUPREMEX KFT.	HU
Itoprid PMCS 50 mg potahované tablety	CZ/H/0356/001	49/625/10-C	PRO.MED.CS PRAHA A.S.	CZ
Itoprid PMCS 50 mg filmom obalené tablety	CZ/H/0356/001	49/0649/11-S	PRO.MED.CS PRAHA A.S.	SK
PROGIT 50 mg plévele dengtos tabletés	CZ/H/0467/001	LT/1/13/3443/005	PRO.MED.CS PRAHA A.S.	LT
Progit 50 mg potahované tablety	CZ/H/0467/001	49/409/12-C	PRO.MED.CS PRAHA A.S.	CZ
PROGIT 50 mg filmom obalené tablet	CZ/H/0467/001	49/0465/13-S	PRO.MED.CS PRAHA A.S.	SK
Prokit, 50 mg, tabletki powlekane	CZ/H/0467/001	21664	PRO.MED.CS PRAHA A.S.	PL
Progit 50 mg plévele dengtos tabletés	CZ/H/0467/001	LT/1/13/3443/001	PRO.MED.CS PRAHA A.S.	LT
Progit 50 mg plévele dengtos tabletés	CZ/H/0467/001	LT/1/13/3443/002	PRO.MED.CS PRAHA A.S.	LT
Progit 50 mg plévele dengtos tabletés	CZ/H/0467/001	LT/1/13/3443/003	PRO.MED.CS PRAHA A.S.	LT
Progit 50 mg plévele dengtos tabletés	CZ/H/0467/001	LT/1/13/3443/004	PRO.MED.CS PRAHA A.S.	LT