



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 February 2023
PRAC/69849/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): itopride

Procedure No. PSUSA/00010606/202206



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
Itomed® 50 mg Filmtabletten	CZ/H/0948/001	141161	PRO.MED.CS PRAHA A.S.	AT
Itomed® 50 mg Filmtabletten	CZ/H/0948/001	141161	PRO.MED.CS PRAHA A.S.	AT
Itoprom 50 mg comprimés pelliculés	CZ/H/0948/001	BE596586	KAPPLER PHARMA CONSULT GMBH	BE
Зирид 50 mg филмирани таблетки	CZ/H/0289/001	20110023	ZENTIVA, K.S.	BG
МЕДОПРИД 50 mg филмирани таблетки	EE/H/0207/001	20160236	MEDOCHEMIE LTD.	BG
Прогит 50 mg филмирани таблетки	CZ/H/0947/001	20220182	KAPPLER PHARMA CONSULT GMBH	BG
Pridaton 50 mg film-coated tablets	not available	023279	CODAL SYNTO LTD	CY
Toprisan 50 mg, επικαλυμμένα με λεπτό υμένιο δισκία	EE/H/0207/001	022533	MEDOCHEMIE LTD.	CY
ASKETON 50 mg potahované tablety	EE/H/0207/001	49/284/16-C	MEDOCHEMIE LTD.	CZ
Itoprid PMCS 50 mg potahované tablety	CZ/H/0356/001	49/625/10-C	PRO.MED.CS PRAHA A.S.	CZ
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	49/252/16-C	XANTIS PHARMA LIMITED	CZ
Itopride Kappler 50 mg potahované tablety	CZ/H/0947/001	49/116/20-C	KAPPLER PHARMA CONSULT GMBH	CZ
Itopride Kappler Pharma 50 mg potahované tablety	CZ/H/0948/001	49/117/20-C	KAPPLER PHARMA CONSULT GMBH	CZ
Kinito 50 mg potahované tablety	CZ/H/0289/001	49/819/10-C	ZENTIVA, K.S.	CZ
Astipal, 50 mg õhukese polümeerikatttega tabletid	EE/H/0207/001	912816	MEDOCHEMIE LTD.	EE

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Gastrix, 50 mg õhukese polümeerikattega tabletid	EE/H/0213/001	913416	MEDOCHEMIE LTD.	EE
Itoprom, 50 mg õhukese polümeerikattega tabletid	CZ/H/0947/001	1051922	PRO.MED.CS PRAHA A.S.	EE
Itoprom, 50 mg õhukese polümeerikattega tabletid	CZ/H/0947/001	1051922	PRO.MED.CS PRAHA A.S.	EE
Progit 50 mg comprimidos recubiertos con película EFG	CZ/H/0947/001	86657	KAPPLER PHARMA CONSULT GMBH	ES
Progit 50 mg kalvopäällysteiset tabletit	CZ/H/0947/001	37980	KAPPLER PHARMA CONSULT GMBH	FI
Progit 50 mg επικαλυμμένα με υμένιο δισκία	CZ/H/0948/001	26927/16-03-2022	KAPPLER PHARMA CONSULT GMBH	GR
Itonorm 50 mg filmom obložene tablete	CZ/H/0948/001	HR-H-721577701	KAPPLER PHARMA CONSULT GMBH	HR
Itopride Kappler Pharma 50 mg film-coated tablets	CZ/H/0948/001	PA1514/004/001	KAPPLER PHARMA CONSULT GMBH	IE
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/001	MEDOCHEMIE LTD.	LT
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/002	MEDOCHEMIE LTD.	LT
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/003	MEDOCHEMIE LTD.	LT
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/004	MEDOCHEMIE LTD.	LT
Zirid 50 mg plėvele dengtos tabletės	CZ/H/0289/001	LT/1/10/2209/001	ZENTIVA, K.S.	LT
Zirid 50 mg plėvele dengtos tabletės	CZ/H/0289/001	LT/1/10/2209/002	ZENTIVA, K.S.	LT
Progit 50 mg comprimés pelliculés	CZ/H/0948/001	2022020041	KAPPLER PHARMA CONSULT GMBH	LU
Progit 50 mg apvalkotās	CZ/H/0947/001	21-0211	PRO.MED.CS PRAHA A.S.	LV

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tabletes				
Progit 50 mg apvalkotās tabletes	CZ/H/0947/001	21-0211	PRO.MED.CS PRAHA A.S.	LV
Toprisan, 50 mg film-coated tablets	EE/H/0207/001	MA032/09501	MEDOCHEMIE LTD.	MT
Prokit, 50 mg, tabletki powlekane	PL/H/0871/001	21664	PRO.MED.CS PRAHA A.S.	PL
Zirid, 50 mg, tabletki powlekane	CZ/H/0289/001	17590	ZENTIVA, K.S.	PL
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/01	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/02	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/03	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/04	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/05	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/06	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/07	MEDOCHEMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/08	MEDOCHEMIE LTD.	RO
ASKETON 50 mg filmom obalené tablety	EE/H/0207/001	49/0337/16-S	MEDOCHEMIE LTD.	SK
Ganaton 50 mg filmom obalené tablety	not available	49/0139/00-S	VIATRIS HEALTHCARE LTD	SK
ITOCAN 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	CANDE S.R.O.	SK
Itoprid PMCS 50 mg filmom obalené tablety	CZ/H/0356/001	49/0649/11-S	PRO.MED.CS PRAHA A.S.	SK
Itoprid Xantis 50 mg tablety	SK/H/0159/001	49/0272/16-S	XANTIS PHARMA LIMITED	SK
Itoprid Xantis 50 mg tablety	SK/H/0159/001	49/0272/16-S	XANTIS PHARMA LIMITED	SK

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Kinito 50 mg filmom obalené tablety	CZ/H/0289/001	49/0792/10-S	ZENTIVA, A.S.	SK