



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2026
EMADOC-1700519818-2915318
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): itopride

EURD list No. PSUSA/00010606/202506

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

An agency of the European Union

© European Medicines Agency, 2025. Reproduction is authorised provided the source is acknowledged.



Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/01	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/02	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/03	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/04	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/05	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/06	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/07	MEDOCHÉMIE LTD.	RO
Asketon 50 mg comprimate filmate	EE/H/0207/001	13789/2021/08	MEDOCHÉMIE LTD.	RO
ASKETON 50 mg filmom obalené tablety	EE/H/0207/001	49/0337/16-S	MEDOCHÉMIE LTD.	SK
ASKETON 50 mg potahované tablety	EE/H/0207/001	49/284/16-C	MEDOCHÉMIE LTD.	CZ
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/001	MEDOCHÉMIE LTD.	LT
ASTIPAL 50 mg plėvele dengtos tabletės	EE/H/0207/001	LT/1/16/3933/002	MEDOCHÉMIE 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
Astipal, 50 mg õhukese polümeerikattega tabletid	EE/H/0207/001	912816	MEDOCHEMIE LTD.	EE
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
GASTRIX 50 mg filmom obalené tablety	EE/H/0213/001	49/0330/16-S	MEDOCHEMIE LTD.	SK
Gastrix, 50 mg õhukese polümeerikattega tabletid	EE/H/0213/001	913416	MEDOCHEMIE LTD.	EE
Itokin, 50 mg, tabletki powlekane	not available	27804	BIOFARM SP. Z O.O.	PL
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855366	KAPPLER PHARMA CONSULT GMBH	PT

Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855374	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855408	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855416	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855424	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855432	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855440	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855366	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855374	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855408	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855416	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855424	KAPPLER PHARMA CONSULT GMBH	PT

Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855432	KAPPLER PHARMA CONSULT GMBH	PT
Itomed 50 mg comprimidos revestidos por película	CZ/H/0947/001	5855440	KAPPLER PHARMA CONSULT GMBH	PT
Itomed® 50 mg Filmtabletten	CZ/H/0948/001	141161	PRO.MED.CS PRAHA A.S.	AT
Itonorm 50 mg filmom obložene tablete	CZ/H/0948/001	HR-H-721577701	PRO.MED.CS PRAHA A.S.	HR
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/252/16-C	FARMAK INTERNATIONAL SP. Z O.O.	CZ
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK

Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.O.	SK
Itoprid FMK 50 mg tablety	SK/H/0159/001	49/0272/16-S	SYMPHAR SP. Z O.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 PMCS 50 mg potahované tablety	CZ/H/0356/001	49/625/10-C	PRO.MED.CS PRAHA A.S.	CZ
Itopride PMCS 50 mg potahované tablety	CZ/H/0948/001	49/117/20-C	PRO.MED.CS PRAHA A.S.	CZ
Itoprom 50 mg comprimés pelliculés	CZ/H/0948/001	BE596586	PRO.MED.CS PRAHA A.S.	BE
Itoprom 50 mg comprimés pelliculés	CZ/H/0948/001	2022020041	PRO.MED.CS PRAHA A.S.	LU
Itoprom 50 mg filmomhulde tabletten	CZ/H/0948/001	BE596586	PRO.MED.CS PRAHA A.S.	BE
Itoprom 50 mg filmomhulde tabletten	CZ/H/0948/001	2022020041	PRO.MED.CS PRAHA A.S.	LU
Itoprom 50 mg Filmtabletten	CZ/H/0948/001	BE596586	PRO.MED.CS PRAHA A.S.	BE
Itoprom 50 mg Filmtabletten	CZ/H/0948/001	2022020041	PRO.MED.CS PRAHA A.S.	LU

Itoprom, 50 mg õhukese polümeerikattega tabletid	CZ/H/0947/001	1051922	PRO.MED.CS PRAHA A.S.	EE
Kinito 50 mg filmom obalené tablety	CZ/H/0289/001	49/0792/10-S	ZENTIVA, A.S.	SK
Kinito 50 mg filmom obalené tablety	CZ/H/0289/001	49/0792/10-S	ZENTIVA, A.S.	SK
Kinito 50 mg filmom obalené tablety	CZ/H/0289/001	49/0792/10-S	ZENTIVA, A.S.	SK
Kinito 50 mg potahované tablety	CZ/H/0289/001	49/819/10-C	ZENTIVA, K.S.	CZ
Predox, 50 mg, tabletki powlekane	not available	27867	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	PL
Pridaton 50 mg film-coated tablets	not available	023279	CODAL SYNTO LTD	CY
Progit 50 mg apvalkotās tabletes	CZ/H/0947/001	21-0211	PRO.MED.CS PRAHA A.S.	LV
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729065	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729077	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729089	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729014	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729026	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729038	PRO.MED.CS PRAHA A.S.	IT

Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729040	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg compresse rivestite con film	CZ/H/0947/001	048729053	PRO.MED.CS PRAHA A.S.	IT
Progit 50 mg comprimidos recubiertos con película EFG	CZ/H/0947/001	86657	KAPPLER PHARMA CONSULT GMBH	ES
Progit 50 mg comprimidos recubiertos con película EFG	CZ/H/0947/001	86657	KAPPLER PHARMA CONSULT GMBH	ES
Progit 50 mg film-coated tablets	CZ/H/0947/001	20220182	KAPPLER PHARMA CONSULT GMBH	BG
Progit 50 mg film-coated tablets	CZ/H/0947/001	20220182	KAPPLER PHARMA CONSULT GMBH	BG
Progit 50 mg filmdragerade tabletter	CZ/H/0947/001	37980	PRO.MED.CS PRAHA A.S.	FI
Progit 50 mg kalvopäällysteiset tabletit	CZ/H/0947/001	37980	PRO.MED.CS PRAHA A.S.	FI
PROGIT 50 mg plevele dengtos tabletes	CZ/H/0948/001	LT/1/22/5086/001	PRO.MED.CS PRAHA A.S.	LT
PROGIT 50 mg plevele dengtos tabletes	CZ/H/0948/001	LT/1/22/5086/002	PRO.MED.CS PRAHA A.S.	LT
PROGIT 50 mg plevele dengtos tabletes	CZ/H/0948/001	LT/1/22/5086/003	PRO.MED.CS PRAHA A.S.	LT
PROGIT 50 mg plevele dengtos tabletes	CZ/H/0948/001	LT/1/22/5086/004	PRO.MED.CS PRAHA A.S.	LT
PROGIT 50 mg plevele dengtos tabletes	CZ/H/0948/001	LT/1/22/5086/005	PRO.MED.CS PRAHA A.S.	LT
PROGIT 50 mg plėvele dengtos tabletės	CZ/H/0948/001	LT/1/22/5086/006	PRO.MED.CS PRAHA A.S.	LT

Progit 50 mg επικαλυμμένα με υμένιο δισκία	CZ/H/0948/001	26927/16-03-2022	KAPPLER PHARMA CONSULT GMBH	GR
Progit, filmovertukne tabletter	CZ/H/0947/001	64303	KAPPLER PHARMA CONSULT GMBH	DK
Progit, filmovertukne tabletter	CZ/H/0947/001	64303	KAPPLER PHARMA CONSULT GMBH	DK
Prokit, 50 mg, tabletki powlekane	PL/H/0871/001	21664	PRO.MED.CS PRAHA A.S.	PL
Refla 50 mg potahované tablety	CZ/H/0947/001	49/116/20-C	PRO.MED.CS PRAHA A.S.	CZ
REFLAD 50 mg film-coated tablets	CZ/H/0948/001	PA2179/003/001	PRO.MED.CS PRAHA A.S.	IE
Toprisan 50 mg, επικαλυμμένα με λεπτό υμένιο δισκία	EE/H/0207/001	022533	MEDOCHEMIE LTD.	CY
Toprisan, 50 mg film-coated tablets	EE/H/0207/001	MA032/09501	MEDOCHEMIE LTD.	MT
Zirid 50 mg plėvele dengtos tabletės	CZ/H/0289/001	LT/1/10/2209/003	ZENTIVA, K.S.	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
Zirid, 50 mg, tabletki powlekane	CZ/H/0289/001	17590	ZENTIVA, K.S.	PL
Зирид 50 mg филмирани таблетки	CZ/H/0289/001	20110023	ZENTIVA, K.S.	BG
Зирид 50 mg филмирани таблетки	CZ/H/0289/001	20110023	ZENTIVA, K.S.	BG

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