19 July 2017
EMA/581726/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: domperidone

Procedure No.: PSUSA/00001158/201611

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**
Domperidone 10mg Tablets	not available	PL 21880/0110	MEDREICH PLC	UK
Peridon 10 mg compresse rivestite con film	not available	024309039	ITALCHIMICI S.P.A.	IT
Peridon 10 mg granulato effervescente	not available	024309130	ITALCHIMICI S.P.A.	IT
Peridon 1 mg/ml sospensione orale	not available	024309142	ITALCHIMICI S.P.A.	IT
Peridon 30 mg supposte	not available	024309066	ITALCHIMICI S.P.A.	IT
DOMPERIDONE PIERRE FABRE 10 mg, comprimé orodispersible	FR/H/0335/001	34009 550 214 7 6	PIERRE FABRE MEDICAMENT	FR
OROPERIDYS 10 mg orodispergeerbare tabletten	FR/H/0335/001	BE329357	PIERRE FABRE MEDICAMENT	BE
DOMPERIDONE PIERRE FABRE 10 mg, comprimé orodispersible	FR/H/0335/001	34009 300 595 2 4	PIERRE FABRE MEDICAMENT	FR
DOMPERIDONE PIERRE FABRE 10 mg, comprimé orodispersible	FR/H/0335/001	34009 398 031 2 8	PIERRE FABRE MEDICAMENT	FR
NEOPERIDYS 10 mg compresse orodispersibili	FR/H/0335/001	039985027	PFM PHARMA / ITALY	IT
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	FR/H/0335/001	20499	PIERRE FABRE MEDICAMENT	CY
NEOPERIDYS 10 mg compresse orodispersibili	FR/H/0335/001	039985015	PFM PHARMA / ITALY	IT
OROPERIDYS 10 mg comprimés orodispersibles	FR/H/0335/001	2009030033	PIERRE FABRE MEDICAMENT	LU
OROPERIDYS 10 mg, suus dispergeeruvad tabletid	FR/H/0335/001	607408	PIERRE FABRE MEDICAMENT	EE
OROPERIDYS 10 mg comprimés orodispersibles	FR/H/0335/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg mute dispergejamas tabletes	FR/H/0335/001	08-0269	PIERRE FABRE MEDICAMENT	LV
OROPERIDYS 10 mg burnoje disperguojamosios tabletes	FR/H/0335/001	LT/1/08/1317/001	PIERRE FABRE MEDICAMENT	LT
Oroperidys, 10 mg, tabletki ulegajace rozpadowi w jamie ustnej	FR/H/0335/001	15213	PIERRE FABRE MEDICAMENT	PL
OROPERIDYS 10 mg comprimate orodispersabile	FR/H/0335/001	4203/2012/01	PIERRE FABRE MEDICAMENT	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**
OROPERIDYS 10 mg tablety dispergovatelné v ústech	FR/H/0335/001	20/652/08-C	PIERRE FABRE MEDICAMENT	CZ
OROPERIDYS 10 mg orodispergovatel'ne tablety	FR/H/0335/001	20/0503/08-S	PIERRE FABRE MEDICAMENT	SK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
MOTILIUM/DOMPERIDONE 10 MG FILM-COATED TABLETS	not available	PL 17780/0300	WINTHROP PHARMACEUTICALS UK LTD	UK
Domperidone 10mg Tablets	not available	PL 44041/0011	NOUMED LIFE SCIENCES	UK
PERIDYS 10 mg, comprimé pelliculé	not available	34009 550 210 7 0	PIERRE FABRE MEDICAMENT	FR
PERIDYS 10 mg, comprimé pelliculé	not available	34009 300 578 6 5	PIERRE FABRE MEDICAMENT	FR
PERIDYS 1 mg/ml, suspension buvable	not available	34009 328 642 2 5	PIERRE FABRE MEDICAMENT	FR
MOTILIUM 1 mg/ml Suspensão oral	BE/H/106/003	9532200	JOHNSON & JOHNSON LDA	PT
Motilium suspensie voor oraal gebruik 1 mg/ml	BE/H/0106/003	RVG 07679	JOHNSON & JOHNSON CONSUMER B.V.	NL
Motilium 1mg/ml Oral Suspension	BE/H/0106/003	PA 823/51/6	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium 10mg Film Coated Tablets	not available	PA 823/51/2	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/0106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
MOTILIUM 1 mg/ml, suspensie voor oraal gebruik �volwassenen�	BE/H/106/003	BE190662	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10 mg Comprimido revestido por película	BE/H/0106/009	9512814	JOHNSON & JOHNSON LDA	PT

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**
MOTILIUM 1 mg/ml Suspensão oral	BE/H/106/003	9532234	JOHNSON & JOHNSON LDA	PT
MOTILIUM 1 mg/ml, suspensie voor oraal gebruik �pediatrie�	BE/H/106/002	BE110013	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10 mg Comprimido revestido por película	BE/H/0106/009	9512822	JOHNSON & JOHNSON LDA	PT
MOTILIUM 1 mg/ml, suspension buvable � adultes �	BE/H/106/003	BE190662	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	BE/H/0106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10mg Film Coated Tablets	not available	PA 823/51/2	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/0106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
MOTILIUM 10 mg, filmomhulde tabletten (domperidon)	BE/H/0106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/0106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
CILROTON 10mg/tab Επικαλυμμένο με λεπτό υμένιο δισκίο	BE/H/0106/009	15084/07.03.2006	JOHNSON & JOHNSON HELLAS CONSUMER AE	GR
MOTILIUM 1 mg/ml suspension buvable « pédiatrie »	BE/H/0106/002	BE110013	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 1 mg/ml suspension buvable � p�diatrie �	BE/H/106/002	2005058774	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés pelliculés (maléate de dompéridone)	BE/H/106/001	2005058771	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
Motilium zetpillen voor kinderen 30 mg	BE/H/0106/004	RVG 07682	JOHNSON & JOHNSON CONSUMER B.V.	NL

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**
MOTILIUM 10 mg, filmomhulde tabletten (domperidonemaleaat)	BE/H/0106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, filmomhulde tabletten (domperidonemaleaat)	BE/H/0106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium Fastmelts 10mg Orodispersible Tablets	not available	PA 823/51/1	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium filmomhulde tabletten 10 mg (domperidonmaleaat)	BE/H/0106/001	RVG 07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
Motilium filmomhulde tabletten 10 mg (domperidonmaleaat)	BE/H/0106/001	RVG 07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
Domperidone JJC filmomhulde tabletten 10 mg	not available	RVG 20544=07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM instant 10 mg, orodispergeerbare tabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM instant 10 mg, orodispergeerbare tabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Domperidone JJC filmomhulde tabletten 10 mg	not available	RVG 20544=07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
Motilium Fastmelts 10mg Orodispersible Tablets	not available	PA 823/51/1	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM instant 10 mg, orodispergeerbare tabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, filmomhulde tabletten (domperidon)	BE/H/106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	BE/H/106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 1 mg/ml Suspension zum Einnehmen �P�diatrie�	BE/H/106/002	BE110013	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE

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**
MOTILIUM 10 mg Filmtabletten (10 mg Domperidon pro Tablette)	BE/H/106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg Filmtabletten (10 mg Domperidon pro Tablette)	BE/H/106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 1 mg/ml Suspension zum Einnehmen "Erwachsene�	BE/H/106/003	BE190662	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/0106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium® Tabletten 10 mg Filmtabletten	DE/H/0415/001	43.00.00	TAKEDA GMBH (KONSTANZ)	DE
Motilium® Tropfen 10 mg/ml Suspension	DE/H/0415/002	43.00.02	TAKEDA GMBH (KONSTANZ)	DE
MOTILIUM 1 mg/ml suspensión oral	not available	55.411	LABORATORIOS DR. ESTEVE S.A.	ES
MOTILIUM 10 mg comprimidos recubiertos con película	not available	55.410	LABORATORIOS DR. ESTEVE S.A.	ES
DOMPERIDONE	not available	PL 17780/0299	WINTHROP PHARMACEUTICALS UK LTD	UK
DOMPERIDONE	not available	PL 17780/0299	WINTHROP PHARMACEUTICALS UK LTD	UK
OROPERIDYS 10 mg, comprimé orodispersible	not available	34009 550 210 4 9	PIERRE FABRE MEDICAMENT	FR
OROPERIDYS 10 mg, comprimé orodispersible	not available	34009 300 578 5 8	PIERRE FABRE MEDICAMENT	FR
MOTILIUM 10 mg, comprimé pelliculé	BE/H/0106/009	34009 336 882-9 5	JANSSEN-CILAG	FR
MOTILIUM 1 mg/ml, suspension buvable	BE/H/0106/002	34009 300 591 1 1	JANSSEN-CILAG	FR
Motilium 10 mg plėvele dengtos tabletės	not available	LT/1/95/0982/002	UAB JOHNSON & JOHNSON	LT
MOTILIUM Potahované tablety	not available	20/813/93-C	JANSSEN-CILAG S.R.O	CZ
Motilium® 10mg tablets	not available	MA018/01605	JANSSEN-CILAG INTERNATIONAL NV	MT
Motilium® 1mg/ml Oral Suspension	not available	018/01604	JANSSEN-CILAG INTERNATIONAL NV	MT
Motilium 1mg/ml Πόσιμο εναιώρημα	not available	7459	JANSSEN-CILAG INTERNATIONAL NV	CY
Motilium, 10 mg δισκία	not available	7224	JANSSEN-CILAG INTERNATIONAL NV	CY

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Motilium	BE/H/0106/001	09662	JANSSEN-CILAG A/S	DK
Motilium 10 mg compresse rivestite con film	BE/H/0106/009	024953034	JANSSEN-CILAG SPA	IT
Motilium 1 mg/ml sospensione orale	BE/H/0106/003	024953022	JANSSEN-CILAG SPA	IT
MOTILIUM 10 mg filmtabletta	not available	OGYI-T-2223/01	JANSSEN-CILAG KFT.	HU
Motilium 10 mg apvalkotās tabletes	not available	98-0800	UAB JOHNSON & JOHNSON	LV
MOTILIUM 10 mg, comprimé pelliculé	BE/H/0106/009	34009 323 411-2 2	JANSSEN-CILAG	FR
MOTILIUM 1 mg/ml, suspension buvable	BE/H/0106/002-003	34009 323 409-8 9	JANSSEN-CILAG	FR
Motilium 10 mg - Filmtabletten	BE/H/0106/009	17412	JANSSEN-CILAG PHARMA GMBH	AT
Motilium 1 mg/ml - Suspension zum Einnehmen	BE/H/0106/003	1-20462	JANSSEN-CILAG PHARMA GMBH	AT
Motilium 10 mg plėvele dengtos tabletės	not available	LT/1/95/0982/001	UAB JOHNSON & JOHNSON	LT
MOTILIUM 10 mg Film-Coated Tablets	not available	20010169	JOHNSON & JOHNSON PRODAJA MEDICINSKIH IN FARMACEVTSKIH IZDELKOV, D.O.O.	BG