9 July 2020
EMA/383847/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: domperidone

Procedure no.: PSUSA/00001158/201911

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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
CILROTON 10mg/tab Επικαλυμμένο με λεπτό υμένιο δισκίο	BE/H/106/009	70681/5-11-2008	JOHNSON & JOHNSON HELLAS CONSUMER AE	GR
CILROTON 5mg/5ml Πόσιμο διάλυμα	BE/H/106/003	57067/07/5-11-2008	JOHNSON & JOHNSON HELLAS CONSUMER AE	GR
Domperidone 10mg Tablets	not available	PL 44041/0011	NOUMED LIFE SCIENCES	UK
Domperidone 10mg Tablets	not available	PL 21880/0110	MEDREICH PLC	UK
Domperidone 1mg/ml Oral Suspension	not available	PL 17780/0299	ZENTIVA PHARMA UK LIMITED	UK
Domperidone JJC filmomhulde tabletten 10 mg	not available	RVG 20544 = 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	BE/H/0106/ 001	09662	JANSSEN-CILAG A/S	DK
MOTILIUM	BE/H/106/003	1069/05058773	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU

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	BE/H/106/002	1069/05058774	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
Motilium 1 mg/ml - Suspension zum Einnehmen	BE/H/0106/ 002,002-003,003	1-20462	JANSSEN-CILAG PHARMA GMBH	AT
Motilium 1 mg/ml sospensione orale	BE/H/0106/ 002,002-003,003	024953022	JANSSEN-CILAG SPA	IT
Motilium 1 mg/ml Suspensão oral	BE/H/106/003	9532200	JOHNSON & JOHNSON LDA	PT
Motilium 1 mg/ml Suspensão oral	BE/H/106/003	9532234	JOHNSON & JOHNSON LDA	PT
MOTILIUM 1 mg/ml suspension buvable « pédiatrie »	BE/H/106/002	BE110013	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 1 mg/ml suspensión oral	not available	55.411	ESTEVE PHARMACEUTICALS, S.A.	ES
MOTILIUM 1 mg/ml Suspension zum Einnehmen „Pädiatrie"	BE/H/106/002	BE110013	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

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, suspensie voor oraal gebruik "pediatrie"	BE/H/106/002	BE110013	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 1 mg/ml, suspensie voor oraal gebruik "volwassenen"	BE/H/106/003	BE190662	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 1 mg/ml, suspension buvable	BE/H/0106/ 002,002-003,003	34009 300 591 1 1	JANSSEN-CILAG	FR
MOTILIUM 1 mg/ml, suspension buvable	BE/H/0106/ 002,002-003,003	34009 323 409 8 9	JANSSEN-CILAG	FR
MOTILIUM 1 mg/ml, suspension buvable « adultes »	BE/H/106/003	BE190662	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10 mg - Filmtabletten	BE/H/0106/ 009	17412	JANSSEN-CILAG PHARMA GMBH	AT
Motilium 10 mg apvalkotās tabletes	not available	98-0800	UAB "JOHNSON & JOHNSON"	LV
Motilium 10 mg compresse rivestite con film	BE/H/0106/ 009	024953034	JANSSEN-CILAG SPA	IT
Motilium 10 mg comprimate filmate	not available	2068/2009/01	TERAPIA 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
Motilium 10 mg comprimate filmate	not available	2068/2009/02	TERAPIA S.A.	RO
Motilium 10 mg Comprimido revestido por película	BE/H/106/009	9512814	JOHNSON & JOHNSON LDA	PT
Motilium 10 mg Comprimido revestido por película	BE/H/106/009	9512822	JOHNSON & JOHNSON LDA	PT
Motilium 10 mg comprimidos recubiertos con película	not available	55.410	ESTEVE PHARMACEUTICALS, S.A.	ES
Motilium 10 mg film-coated tablets	not available	20010169	JOHNSON & JOHNSON D.O.O.	BG
Motilium 10 mg film-coated tablets	not available	PL 17780/0300	ZENTIVA PHARMA UK LIMITED	UK
MOTILIUM 10 mg filmtabletta	not available	OGYI-T-2223/01	JANSSEN-CILAG KFT.	HU
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

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 (12,72 mg Domperidon-Maleat = 10 mg Domperidon pro Tablette)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg Filmtabletten (12,72 mg Domperidon-Maleat = 10 mg Domperidon pro Tablette)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10 mg plėvele dengtos tabletės	not available	LT/1/95/0982/002	UAB "JOHNSON & JOHNSON"	LT
Motilium 10 mg plėvele dengtos tabletės	not available	LT/1/95/0982/001	UAB "JOHNSON & JOHNSON"	LT
MOTILIUM 10 mg potahované tablety	not available	20/813/93-C	JANSSEN-CILAG S.R.O	CZ
MOTILIUM 10 mg, comprimé pelliculé	BE/H/0106/ 009	34009 336 882-9 5	JANSSEN-CILAG	FR
MOTILIUM 10 mg, comprimé pelliculé	BE/H/0106/ 009	34009 300 612 6 8	JANSSEN-CILAG	FR

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, comprimé pelliculé	BE/H/0106/009	34009 323 411-2 2	JANSSEN-CILAG	FR
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés orodispersibles	BE/H/106/008	2005059999	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	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

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, comprimés pelliculés (dompéridone)	BE/H/106/009	BE272167	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	BE/H/106/009	2008120046	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	BE/H/106/009	2008120046	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés pelliculés (dompéridone)	BE/H/106/009	2008120046	JOHNSON & JOHNSON CONSUMER N.V./S.A.	LU
MOTILIUM 10 mg, comprimés pelliculés (maléate de dompéridone)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés pelliculés (maléate de dompéridone)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, comprimés pelliculés (maléate de dompéridone)	BE/H/106/001	2005058771	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 10 mg, filmomhulde tabletten (domperidon)	BE/H/106/009	BE272167	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, filmomhulde tabletten (domperidon)	BE/H/106/009	BE272167	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, filmomhulde tabletten (domperidonmaleaat)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM 10 mg, filmomhulde tabletten (domperidonmaleaat)	BE/H/106/001	BE109986	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium 10mg Film Coated Tablets	not available	PA 330/40/2	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Motilium 10mg Film Coated Tablets	not available	PA 330/40/2	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Motilium 1mg/ml Oral Suspension	BE/H/106/003	PA 823/51/6	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium Fastmelts 10mg Orodispersible Tablets	not available	PA 330/40/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Motilium Fastmelts 10mg Orodispersible Tablets	not available	PA 330/40/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE

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 Fastmelts 10mg Orodispersible Tablets	not available	PA 330/40/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Motilium Fastmelts 10mg Orodispersible Tablets	not available	PA 330/40/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Motilium filmomhulde tabletten 10 mg (domperidonmaleaat)	BE/H/106/001	RVG 07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
Motilium filmomhulde tabletten 10 mg (domperidonmaleaat)	BE/H/106/001	RVG 07678	JOHNSON & JOHNSON CONSUMER B.V.	NL
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM Instant 10 mg Schmelztabletten	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM instant 10 mg, orodispergeerbare tabletten	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
MOTILIUM instant 10 mg, orodispergeerbare tabletten	BE/H/106/008	BE274827	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 instant 10 mg, orodispergeerbare tabletten	BE/H/106/008	BE274827	JOHNSON & JOHNSON CONSUMER N.V./S.A.	BE
Motilium suspensie voor oraal gebruik 1 mg/ml	BE/H/106/003	RVG 07679	JOHNSON & JOHNSON CONSUMER B.V.	NL
Motilium, 10 mg δισκία	not available	7224	JANSSEN-CILAG INTERNATIONAL NV	CY
Motilium® 10mg tablets	not available	MA018/01605	JANSSEN-CILAG INTERNATIONAL NV	MT
Motilium® Tabletten 10 mg Filmtabletten	DE/H/0415/001	43.00.00	TAKEDA GMBH	DE
Motilium® Tropfen 10 mg/ml Suspension	DE/H/0415/002	43.00.02	TAKEDA GMBH	DE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Motilium®Rx 10 mg Film-coated Tablets	BE/H/106/009	PA 823/51/7	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE

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 burnoje disperguojamosios tabletės	EL/H/0285/001	LT/1/08/1317/002	PIERRE FABRE MEDICAMENT	LT
Oroperidys 10 mg burnoje disperguojamosios tabletės	EL/H/0285/001	LT/1/08/1317/003	PIERRE FABRE MEDICAMENT	LT
Oroperidys 10 mg burnoje disperguojamosios tabletės	EL/H/0285/001	LT/1/08/1317/001	PIERRE FABRE MEDICAMENT	LT
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	0509633	PIERRE FABRE MEDICAMENT	LU
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	0822919	PIERRE FABRE MEDICAMENT	LU
OROPERIDYS 10 mg comprimés orodispersibles	EL/H/0285/001	0636721	PIERRE FABRE MEDICAMENT	LU

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 orodispergeerbare tabletten	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg orodispergeerbare tabletten	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
OROPERIDYS 10 mg orodispergeerbare tabletten	EL/H/0285/001	BE329357	PIERRE FABRE MEDICAMENT	BE
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
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	20499	PIERRE FABRE MEDICAMENT	CY
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	20499	PIERRE FABRE MEDICAMENT	CY
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	20499	PIERRE FABRE MEDICAMENT	CY
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	45832/6-7-2012	PIERRE FABRE FARMAKA SA	GR

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, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	45832/6-7-2012	PIERRE FABRE FARMAKA SA	GR
OROPERIDYS 10 mg, δισκία διασπειρόμενα στο στόμα	EL/H/0285/001	45832/6-7-2012	PIERRE FABRE FARMAKA SA	GR
Peridon 1 mg/ml sospensione orale	not available	024309142	ITALCHIMICI S.P.A.	IT
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 30 mg supposte	not available	024309066	ITALCHIMICI S.P.A.	IT
PERIDYS 1 mg/ml, suspension buvable	not available	34009 328 642 2 5	PIERRE FABRE MEDICAMENT	FR
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

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
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200011	CRINOS S.P.A.	IT
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200062	CRINOS S.P.A.	IT
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200035	CRINOS S.P.A.	IT
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200023	CRINOS S.P.A.	IT
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200047	CRINOS S.P.A.	IT
RAXAR 10 mg compresse orodispersibili	FR/H/0364/001	039200050	CRINOS S.P.A.	IT