

Annex I

List of the names, pharmaceutical form(s), strength(s) of the medicinal product(s), route(s) of administration, marketing authorisation holder(s) in the member states

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 1020 Wien Austria	Metogastron 10 mg - Ampullen	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 1020 Wien Austria	Metogastron 4 mg/ml - Tropfen	4mg/ml	Oral drops, solution	Oral use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin - Filmtabletten	10mg	Film-coated tablet	Oral use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 10 mg - Ampullen	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 50 mg - Konzentrat zur Infusionsbereitung	50mg/10ml	Concentrate for solution for infusion	Intravenous use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 4 mg/ml - Tropfen	4mg/ml	Oral drops, solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10mg	Tablet	Oral use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	1mg/ml	Oral solution	Oral use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan 20 mg	20mg	Suppository	Rectal use
Belgium	Takeda Belgium Gentsesteenweg 615 1080 Brussel Belgium	Dibertil	5mg	Capsule, soft	Oral use
Belgium	Takeda Belgium Gentsesteenweg 615 1080 Brussel Belgium	Dibertil	10mg	Capsule, soft	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Sopharma PLC 16 Iliensko Shosse Str. Sofia 1220 Bulgaria	Antiemetin	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Bulgaria	Sopharma PLC 16 Iliensko Shosse Str. Sofia 1220 Bulgaria	Antiemetin	5mg/ml	Syrup	Oral use
Bulgaria	AWD.pharma GmbH&Co.KG Wasastrasse 50 Radebeul 01445 Germany	Cerucal	10mg	Tablet	Oral use
Bulgaria	Lek Pharmaceuticals d.d. Verovskova 57 Ljubljana 1526 Slovenia	Degan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Bulgaria	Lek Pharmaceuticals d.d. Verovskova 57 Ljubljana 1526 Slovenia	Degan	10mg	Tablet	Oral use
Bulgaria	CSC Pharmaceuticals Ltd. 10 Assen Yordanov str. Sofia 1592 Bulgaria	Pramidin 10	10 mg/spray	Nasal spray, solution	Nasal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	CSC Pharmaceuticals Ltd. 10 Assen Yordanov str. Sofia 1592 Bulgaria	Pramidin 20	20 mg/spray	Nasal spray, solution	Nasal use
Bulgaria	Alkaloid Ltd 2 Ricardo Vakarini str. Sofia 1404 Bulgaria	Reglan	10mg	Tablet	Oral use
Cyprus	Sanofi Aventis Cyprus Ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan for adults suppository 20mg	20mg	Suppository	Rectal use
Cyprus	Sanofi Aventis Cyprus Ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan solution for injection 10mg/2ml	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Cyprus	Sanofi Aventis Cyprus Ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan tablets 10mg	10mg	Tablet	Oral use
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos street P.O.BOX 51409 3505 Lemesos Cyprus	Elitan tablets 10mg	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	Medochemie ltd 1-10 Constantinoupoleos street P.O.BOX 51409 3505 Lemesos Cyprus	Elitan injection 10mg/2ml	10mg/2ml	Injection	Intramuscular use Intravenous use
Cyprus	Remedica ltd Aharnon street P.O.Box 51706 3508 Lemesos Cyprus	Cloperan tablets 10mg	10mg	Tablet	Oral use
Cyprus	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide Accord 10 mg tablet	10mg	Tablet	Oral use
Czech Republic	Lek Pharmaceuticals d.d. Verovškova 57 1526 Ljubljana Slovenia	Degan 10 mg tablety	10mg	Tablet	Oral use
Czech Republic	Lek Pharmaceuticals d.d. Verovškova 57 1526 Ljubljana Slovenia	Degan 10 mg roztok pro injekci	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Czech Republic	Hexal AG Industriestrasse 25 83607 Holzkirchen Germany	Mcp hexal 10	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Cerucal	10mg	Tablet	Oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Cerucal	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Denmark	Sanofi-aventis Denmark A/S Slotsmarken 13 DK-2970 Hørsholm Denmark	Primperan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Denmark	Sanofi-aventis Denmark A/S Slotsmarken 13 DK-2970 Hørsholm Denmark	Primperan	20mg	Suppository	Rectal use
Denmark	Orion Corporation Orionintie 1A FI-02200 Espoo Finland	Emperal	10mg	Tablet	Oral use
Denmark	Temmler Pharma GmbH & Co KG, Temmlerstrasse 2 DE-35039 Marburg Germany	Gasto-Timelets	30mg	Prolonged-release capsule, hard	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	CERUCAL	10mg	Tablet	Oral use
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	20mg	Suppository	Rectal use
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	10mg	Tablet	Oral use
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	5mg/ml	Solution for injection	Intramuscular use Intravenous use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg, comprimé sécable	10mg	Tablet	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg, suppositoire sécable	10mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 20 mg, suppositoire	20mg	Suppository	Rectal use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN ENFANTS 2,6 mg/ml, solution buvable	2,6mg/ml	Oral solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN NOURRISSONS ET ENFANTS 2,6 mg/ml, solution buvable	2,6mg/ml	Oral drops, solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 0,1% ADULTES, solution buvable édulcorée au cyclamate de sodium et à la saccharine sodique	0.10%	Oral drops, solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 0,1%, solution buvable édulcorée à la saccharine sodique	0.10%	Oral solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg/2 ml, solution injectable en ampoule	10mg/2ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 100 mg, solution injectable	100mg/5ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	CHLORHYDRATE DE METOCLOPRAMIDE RENAUDIN 10 mg/2 ml, solution injectable en ampoule	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	CHLORHYDRATE DE METOCLOPRAMIDE RENAUDIN 20 mg/ml, solution injectable	20mg/ml	Solution for injection	Intramuscular use Intravenous use
France	Panpharma ZI du Clairay Luitré 35133 Fougères France	DICHLORHYDRATE DE METOCLOPRAMIDE PANPHARMA 100 mg/5 ml, solution injectable (IM, IV) en ampoule	100mg/100 ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoires Richard rue du Progrès ZI des Reys de Saulce 26270 Saulce sur Rhone France	CHLORHYDRATE DE METOCLOPRAMIDE RICHARD 1 mg/ml, solution buvable	1mg/ml	Oral solution	Oral use
France	Mylan SAS 117, allée des Parcs 69800 Saint-Priest France	METOCLOPRAMIDE MYLAN 10 mg, comprimé sécable	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	METOCLOPRAMIDE SANDOZ 10 mg, comprimé sécable	10mg	Tablet	Oral use
France	Meda Pharma France 25, boulevard de l'Amiral Bruix 75016 Paris France	ANASIN METOCLOPRAMIDE 15 mg, comprimé à libération prolongée	15mg	Prolonged-release tablet	Oral use
France	Techni-Pharma 7, rue de l'Industrie BP 717 98014 Monaco Cedex Monaco	PROKINYL L.P. 15 mg, gélule à libération prolongée	15mg	Prolonged-release capsule, hard	Oral use
Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching Germany	MCP Tropfen-1 A-Pharma	4.21mg/1g	Oral solution	Oral use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin 10mg/2ml Ampullen	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin 50mg/10ml Ampullen	50mg/10ml	Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin Filmtabletten	10mg	Film-coated tablet	Oral use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin Tropfen	4mg/ml	Oral solution	Oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	MCP AbZ 5 mg/ml Tropfen	5.91mg/ml	Oral solution	Oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL 10	10.53mg	Tablet	Oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL retard	30mg	Prolonged-release capsule, hard	Oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL Tropfen	4.21mg/1ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul Germany	Cerucal inject	10.54mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul Germany	Metoclopramid AWD 10 mg Tabletten	10.53mg	Tablet	Oral use
Germany	axcount Generika AG Max-Planck-Str. 36b D-61381 Friedrichsdorf Germany	MCP axcount Tropfen	4.21mg/ml	Oral solution	Oral use
Germany	betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	MCP-beta Tropfen	4.21mg/ml	Oral solution	Oral use
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 10mg/2ml Ampullen	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 30mg Retardkapseln	30mg	Prolonged-release capsule, hard	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 4mg/1ml Tropfen	5.2mg/ml	Oral solution	Oral use
Germany	DOCPHARM Arzneimittelvertrieb GmbH & Co Greschbachstr. 7 D-76229 Karlsruhe Germany	Metoclopramid Injektionslösung 10ml PB	52.65mg/10ml	Solution for injection	Intravenous use
Germany	Dolorgiet GmbH & Co.KG Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	465mg/100ml	Oral solution	Oral use
Germany	Dolorgiet GmbH & Co.KG Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	8.92mg	Tablet	Oral use
Germany	hameln pharmaceuticals GmbH Langes Feld 13 D-31789 Hameln Germany	Metoclo-hameln 5mg/ml, Injektionslösung	10.53mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg	Gastrosil 10mg Amp.	10mg/2ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil 20 mg Supp.	20mg	Suppository	Rectal use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil 50mg Amp.	52.7mg/10ml	Solution for injection	Intravenous use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil akut Tropfen	5.97mg/ml	Oral solution	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil retard	31.6mg	Prolonged-release capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil retard mite	15.8mg	Prolonged-release capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil Tabletten	10.54mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrsasil Tropfen	5.97mg/ml	Oral solution	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	MCP Heumann 10mg Tabletten	10.53mg	Tablet	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal 10	10.53mg	Tablet	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal injekt	10.53mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Tropfen	4.21mg/ml	Oral solution	Oral use
Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt Germany	MCP dura 4 mg/ml Tropfen zum Einnehmen	4.21mg/ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 10 mg Tabletten	11.82mg	Tablet	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 10mg Zäpfchen	10mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-Ratiopharm 30 mg Retardkapseln	30mg	Prolonged-release capsule	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 4 mg/ml Tropfen	5.2mg/ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm SF 10mg/2ml Injektionslösung	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm SF 50 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	50mg/10ml	Concentrate for solution for infusion	Intravenous use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen	MCP Sandoz 10mg Tabletten	10.53mg	Tablet	Oral use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen Germany	MCP Sandoz 4mg/ml Tropfen zum Einnehmen, Lösung	4.21mg/ml	Oral solution	Oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel Germany	MCP STADA 10 mg Tabletten	10.53mg	Tablet	Oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel Germany	MCP STADA 4mg/1ml Tropfen zum Einnehmen, Lösung	4.21mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Temmler Pharma GmbH & Co.KG Temmlerstr. 2 D-35039 Marburg Germany	Cerucal	10.54mg	Tablet	Oral use
Germany	Temmler Pharma GmbH & Co.KG Temmlerstr. 2 D-35039 Marburg Germany	Cerucal retard	30mg	Prolonged-release capsule, hard	Oral use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10mg	Suppository	Rectal use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	20mg	Suppository	Rectal use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	5mg/5ml	Syrup	Oral use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	AWD Pharma GmbH&Co. KG Wasastrasse 50 Radebeul 1445 Germany	CERUCAL 5 mg/ml oldatos injekció	5mg/ml	Solution for injection	Parenteral use
Hungary	AWD Pharma GmbH&Co. KG Wasastrasse 50 Radebeul 1445 Germany	CERUCAL tabletta	10mg	Tablet	Oral use
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	10mg	Tablet	Oral use
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	20mg	Suppository	Rectal use
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Ireland	Mercury Pharmaceuticals (Ireland) Ltd 4045 Kingswood Road Citywest Business Park Co. Dublin Ireland	Metoclopramide	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Ireland	Amdipharm Limited Regency House Miles Gray Road Basildon Essex, SS14 3AF United Kingdom	Maxolon	5mg/ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Amdipharm Limited Regency House Miles Gray Road Basildon Essex, SS14 3AF United Kingdom	Maxolon	10mg	Tablet	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	1mg/ml	Syrup	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	4mg/ml	Oral drops, solution	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	10mg	Tablet	Oral use
Italy	Teofarma srl Via Fratelli Cervi, 8 27010 Valle Salimbene Pavia Italy	RANDUM	10mg	Tablet	Oral use
Italy	F.I.R.M.A. spa Via Scandicci, 37 50143 Firenze Italy	CLOPAN	10mg	Solution for injection	Intramuscular use Intravenous use
Italy	Sirton Medicare spa Piazza XX Settembre, 2 22079 Villa Guardia - COMO Italy	PRAMIDIN	10 mg/spray	Nasal spray, solution	Nasal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	Sirton Medicare spa Piazza XX Settembre, 2 22079 Villa Guardia - COMO Italy	PRAMIDIN	20 mg/spray	Nasal spray, solution	Nasal use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	DIGESTIVO S.PELLEGRINO	5mg	Effervescent tablet	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	DIGESTIVO S.PELLEGRINO	5mg	Effervescent granules	Oral use
Italy	Hospira Italia srl Via Orazio, 20/22 80122 NAPOLI Italy	METOCLOPRAMIDE CLORIDRATO HOSPIRA	10mg	Solution for injection	Intramuscular use Intravenous use
Italy	Farmakopea spa Via Cavriana, 14 20134 MILANO Italy	ISAPRANDIL	5mg	Effervescent tablet	Oral use
Italy	Farmakopea spa Via Cavriana, 14 20134 MILANO Italy	ISAPRANDIL	5mg	Effervescent granules	Oral use
Latvia	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma 10 mg tablets	10mg	Tablet	Oral use
Latvia	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma 10 mg/2 ml solution for injection	10mg/2ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cerucal 10 mg tablets	10mg	Tablet	Oral use
Lithuania	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cerucal	10mg	Tablet	Oral use
Lithuania	Medochemie Ltd. p.o box 51409 CY-3505, Limassol Cyprus	ELITAN	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Lithuania	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma	10mg	Tablet	Oral use
Lithuania	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Nycomed Belgium s.a. 615, chaussee de Gand B-1080 Bruxelles Belgium	Dibertil	10mg	Capsule, soft	Oral use
Luxembourg	Nycomed Belgium s.a. 615, chaussee de Gand B-1080 Bruxelles Belgium	Dibertil	5mg	Capsule, soft	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Dolorgiet GmbH&Co Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	4,65mg/ml	Oral drops	Oral use
Luxembourg	Dolorgiet GmbH&Co Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	8,92mg	Tablet	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	5,2mg	Oral drops	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	10mg	Suppository	Rectal use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	10mg	Tablet	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	mcP Ratiopharm SF	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm-30	30mg	Modified-release capsule, soft	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Eurogenerics s.a. Heizel Esplanade B22 1020 Laeken Belgium	Metoclopramide EG-10	10mg	Capsule, soft	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan adultes	20mg	Suppository	Rectal use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal-10	10mg	Tablet	Oral use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Injekt	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Tropfen	4mg/ml	Oral drops	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10mg	Tablet	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	1mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Malta	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide 10 mg tablets	10mg	Tablet	Oral use
Malta	Antigen International Limited Chandler House Castle Street, Roscrea County Tipperary Ireland	Metoclopramide Injection BP 10mg/2ml Solution for Injection	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Malta	Hameln Pharmaceuticals Ltd. Nexus, Gloucester Business Park Gloucester GL3 4AG United Kingdom	Metoclopramide 5 mg/ml Injection	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Malta	Medochemie Limited 1-10 Constantinoupleos Str 3011 Limassol Cyprus	Elitan 10mg tablet	10mg	Tablet	Oral use
Malta	Medochemie Ltd. 1-10, Constantinoupleos Street 3011 Limassol Cyprus	Elitan Injection, 10mg/2ml, Solution for Injection	10mg	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Malta	Remedica Ltd. Limassol Industrial Estate Aharnon Street P.O. Box 51706 3508 Limassol Cyprus	Cloperan 10	10mg	Tablet	Oral use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan injectie 10/2 ml, oplossing voor injection 10 mg/2 ml	10mg/2ml	Solution for injection	Intravenous use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan drank, drank 1 mg/ml	1mg/ml	Oral solution	Oral use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan 10, zetpillen 10 mg	10mg	Suppository	Rectal use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan 20, zetpillen 20 mg	20mg	Suppository	Rectal use
Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Metoclopramide HCl 10 PCH, tabletten 10 mg	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten Leur The Netherlands	Metoclopramide HCl CF 10 mg, tabletten	10mg	Tablet	Oral use
Netherlands	Accord Healthcare B.V. De Waterman 15 A 4891 TL Rijsbergen The Netherlands	Metoclopramidemonohydrochlor ide Accord 10 mg Tabletten	10mg	Tablet	Oral use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	20mg	Suppository	Rectal use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	100 mg/ml	Concentrate for solution for infusion	Intravenous use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	1mg/ml	Oral solution	Oral use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Zakłady Farmaceutyczne Polpharma SA ul. Pelplińska 19 83-200 Starogard Gdański Poland	Metoclopramidum 0,5% Polpharma	5mg/ml	Solution for injection	Intramuscular use Intravenous use
Poland	Zakłady Farmaceutyczne Polpharma SA ul. Pelplińska 19 83-200 Starogard Gdański Poland	Metoclopramidum Polpharma	10mg	Tablet	Oral use
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros Portugal	Metoclopramida Labesfal	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros Portugal	Metoclopramida Labesfal	10mg	Tablet	Oral use
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	1mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	10mg	Tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. I Ribeiro de Pavia, 1 - 1º - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	10mg	Tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	2,6mg/ml	Oral drops, solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	1mg/ml	Oral solution	Oral use
Romania	S.C. LAROPHARM S.R.L. Șos. Alexandriei, nr 145 A B07-Bragadiru, jud Ilfov România	METOCLOPRAMID LAROPHARM	10mg	Tablet	Oral use
Romania	S.C. SLAVIA PHARM S.R.L. B-dul Theodor Pallady nr. 44C Sector 3, București 032266 România	METOCLOPRAMID	10mg	Tablet	Oral use
Romania	S.C. MEDUMAN S.A. Str. Aleea Eroilor nr. 28, Vișeu de Sus, Județul Maramureș 435700 România	N - METOCLOPRAMID	10mg	Tablet	Oral use
Romania	S.C. ARENA GROUP S.A Str. Stefan Mihaileanu, nr.31 sector 2; Bucuresti 024022 România	METOCLOPRAMID ARENA 10 mg	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	S.C. TERAPIA S.A. Str. Fabricii nr. 124 Cluj - Napoca 400632 România	METOCLOPRAMID 10 mg	10mg	Tablet	Oral use
Romania	S.C. BIOFARM S.A. Str. Logofăt Tăutu, nr. 99 sector 3, Bucureşti 031212 Romania	METOCLOPRAMID BIOFARM 1mg/5ml	1mg/5ml	Syrup	Oral use
Romania	S.C. BIOFARM S.A. Str. Logofăt Tăutu, nr. 99 sector 3, Bucureşti 031212 Romania	METOCLOPRAMID	7mg/ml	Oral drops, solution	Oral use
Romania	S.C. TERAPIA S.A. Str. Fabricii nr. 124 Cluj - Napoca 400632 România	METOCLOPRAMID 10 mg	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Romania	Accord Healthcar Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramid Accord 10 mg comprimate	10mg	Tablet	Oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26 82102 Bratislava Slovakia	Cerucal	10mg	Tablet	Oral use
Slovak Republic	AWD. pharma GmbH & Co.KG Wasastr. 50 01445 Radebeul Germany	Cerucal	10mg/2ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Sandoz Pharmaceuticals d.d. Verovškova 57 1000 Ljubljana Slovenia	DEGAN 10 mg	10mg	Tablet	Oral use
Slovak Republic	Sandoz Pharmaceuticals d.d. Verovškova 57 1000 Ljubljana Slovenia	DEGAN 10 mg/2 ml	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Slovenia	Alkaloid-INT d.o.o. Ljubljana Slandrova ulica 4 1231 Ljubljana- Crnuce Slovenia	Reglan 1 mg/1 ml peroralna raztopina	1mg/ml	Oral solution	Oral use
Slovenia	Alkaloid-INT d.o.o. Ljubljana Slandrova ulica 4 1231 Ljubljana- Crnuce Slovenia	Reglan 10 mg tablete	10mg	Tablet	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 10 mg/2 ml SOLUCION INYECTABLE	10mg/2ml	Solution for injection	Intramuscular use Intravenous use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 1mg/1ml SOLUCION ORAL	1mg/ml	Oral solution	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 10 mg COMPRIMIDOS	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 260mg/100 ml GOTAS	2,6mg/ml	Oral drops, solution	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 100 mg/5 ml SOLUCION INYECTABLE	100mg/5ml	Solution for injection	Intramuscular use Intravenous use
Spain	Kern Pharma, S.L. Venus, 72. Poligono Industrial Colon II. 08228 Tarrasa Spain	METOCLOPRAMIDA KERN PHARMA 1 mg/ml SOLUCION ORAL	1mg/ml	Oral solution	Oral use
Spain	Pensa Pharma, S.A.U Jorge Comín (médico pediatra) 3 - 46015 Valencia Spain	METOCLOPRAMIDA PENSA 1 mg/ml SOLUCION ORAL	1mg/ml	Oral solution	Oral use
Spain	Accord Healthcare, S.L.U. Moll de Barcelona s/n World Trade Centre Edifici Est 6ª planta 08039 Barcelona Spain	METOCLOPRAMIDA ACCORD 10 mg COMPRIMIDOS	10mg	Tablet	Oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	10mg	Tablet	Oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	10mg/2ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	20mg	Suppository	Rectal use
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North evon EX32 8NS United Kingdom	Metoclopramide Tablets BP 10mg	10mg	Tablet	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon SR	15mg	Modified-release capsules, hard	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon Tablets 10mg	10mg	Tablet	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon Injection 5mg/ml	0.5% w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon High Dose 100mg/20ml	0.5% w/v	Solution for injection	Intravenous use
United Kingdom	Chelonia Healthcare Limited Boumpoulinas 11, 3rd Floor Nicosia, CY-1060 Cyprus	Metoclopramide 10mg Tablets	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Crescent Pharma Limited Units 3 & 4 Quidhampton Business Units Polhampton Lane, Overton Hampshire RG25 3ED United Kingdom	Metoclopramide 10mg Tablets	10mg	Tablet	Oral use
United Kingdom	Ennogen Limited 78 York Street London W1H 1DP United Kingdom	Metoclopramide 10mg Tablets	10mg	Tablet	Oral use
United Kingdom	Ennogen Limited 78 York Street London W1H 1DP United Kingdom	Metoclopramide 5mg/ml Injection	0.5% w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Generics (United Kingdom) Limited Station Close, Potters Bar Hertfordshire EN6 1TL United Kingdom	Metoclopramide Tablets 10mg	10mg	Tablet	Oral use
United Kingdom	Hameln Pharmaceuticals Limited Nexus, Gloucester Business Park Gloucester GL3 4AG United Kingdom	Metoclopramide Injection BP 5mg/ml	0.526% w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Metwest Pharmaceuticals Limited 15 Runnelfield Harrow on the Hill Middlesex HA1 3NY United Kingdom	Metoclopramide 10mg Tablets	10mg	Tablet	Oral use
United Kingdom	Pharmvit Limited 177 Bilton Road, Perivale Middlesex UB6 7HQ United Kingdom	Metoclopramide Tablets BP 10mg	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Rosemont Pharmaceuticals Limited Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds, W Yorkshire LS11 9XE United Kingdom	Metoclopramide Hydrochloride 5mg/5ml Oral Solution	5mg/5ml	Oral solution	Oral use
United Kingdom	Rosemont Pharmaceuticals Limited Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds, W Yorkshire LS11 9XE United Kingdom	Maxolon Paediatric Liquid	5mg/5ml	Oral solution	Oral use
United Kingdom	Teva United Kingdom Limited Brampton Road Hampden Park, Eastbourne East Sussex BN22 9AG United Kingdom	Primperan; Metoclopramide Tablets BP 10mg	10mg	Tablet	Oral use
United Kingdom	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide Hydrochloride 10 mg tablets	10mg	Tablet	Oral use
United Kingdom	Mercury Pharma International Limited 4045 Kingswood Road City West Business Park County Dublin Ireland	Metoclopramide 5mg/ml solution for injection	5mg/ml	Solution for injection	Intramuscular use Intravenous use