

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer 50 mg/ml Injektionslösung und Infusionslösung	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Austria	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject 50 mg Eisen/ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	50mg/ml	Solution for injection/infusion	Intravenous use
Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn Germany	Iron sucrose complex	FerMed 100 mg/5 ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Austria	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic 20 mg/ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Austria	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer 100 mg/ml Injektions- oder Infusionslösung	100mg/ml	Solution for injection/infusion	Intravenous use

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Austria	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Iron sucrose complex	Venofer 20 mg/ml - Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Belgium	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use
Belgium	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monover	100mg/ml	Solution for injection/infusion	Intravenous use
Belgium	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Belgium	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric Carboxymaltose	Injectafer	50.00 mg/ml	Solution for injection/infusion	Intravenous use
Bulgaria	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use

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Bulgaria	Pharmalog AG, 33 Cherni vrah blvd., 1421 Sofia Bulgaria	Iron sucrose complex	Idafer	20mg/ml	Solution for injection	Intravenous use
Bulgaria	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection	Intravenous use
Bulgaria	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
Cyprus	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	ferric carboxymaltose	FERINJECT SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	50mg/ml	Solution for injection/infusion	Intravenous use
Cyprus	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MONOFER SOLUTION FOR INJECTION OR INFUSION 100MG/ML	100mg/ml	Solution for injection/infusion	Intravenous use
Cyprus	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	COSMOFER SOLUTION FOR INJECTION OR INFUSION 50MG IRON/ML	50mg/ml	Solution for injection/infusion	Intravenous use

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Cyprus	The Star Medicines Importers & co ltd, 9A Loukis Akritas Street, P.O.box 50151, 3601 Lemesos, Cyprus	Iron sucrose complex	VENOFER INJECTION 100MG IRON/5ML	100mg/5ml	Solution for injection	Intravenous use
Cyprus	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FERROLOGIC SOLUTION FOR INJECTION/CONCENTRATE FOR SOLUTION FOR INFUSION 20MG/ML	20mg/ml	Solution for injection/infusion	Intravenous use
Czech Republic	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER	20mg/ml	Solution for injection	Intravenous use
Czech Republic	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FERROLOGIC 20 MG/ML	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Czech Republic	PHARMABIDE LTD 20, Lakonias str, 15234 Halandri Athens - Greece	Iron sucrose complex	IRON SUCROSE PHARMABIDE 20 MG/ML	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

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Czech Republic	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	FERION 20 MG/ML	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Czech Republic	Sanofi-Aventis, s.r.o. Evropská 846/176a 160 00 Praha 6 Czech Republic	sodium ferric gluconate complex	FERRLECIT	12.5mg/ml	Solution for injection	Intravenous use
Czech Republic	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	ferric carboxymaltose	FERINJECT	50mg/ml	Solution for injection/infusion	Intravenous use
Denmark	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use
Denmark	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use
Denmark	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	Ferion	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Denmark	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Denmark	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Jerndextran "Pharmacosmos"	50mg/ml	Solution for injection/infusion	Intravenous use
Denmark	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MonoFer	100mg/ml	Solution for injection/infusion	Intravenous use
Denmark	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Estonia	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

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Estonia	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic 20mg/ml	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Estonia	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	Ferion	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Estonia	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Estonia	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
Estonia	Lek Pharmaceuticals d.d. Verovškova 57 1526 Ljubljana Slovenia	Iron (III) hydroxide dextran complex	Ferrum Lek	50mg/ml	Solution for injection	Intramuscular use
Finland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Finland	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Finland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Finland	Alternova A/S Lodshusvej 11 4230 Skaelskoer Denmark	Iron sucrose complex	Venotrix	20mg/ml	Concentrate for solution for infusion/solution for injection	Intravenous use
Finland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use
Finland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
France	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric Carboxymaltose	FERINJECT 50 mg/ml, solution injectable/pour perfusion	50mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER 20mg/ml, solution injectable	20mg/ml	Solution for injection	Intravenous use
France	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	FERRISAT 50 mg/ml, solution injectable ou pour perfusion	50mg/ml	Solution for injection/infusion	Intravenous use
France	Pharmaki Generics Ltd 5 Bourlet Close W1W 7BL London United Kingdom	Iron sucrose complex	FER ACTAVIS 100 mg/5 ml, solution injectable	100mg/5ml	Solution for injection	Intravenous use
France	IBD3 Pharma Consulting Immeuble l'Orient 10, place Charles Béraudier 69003 Lyon France	Iron sucrose complex	FER IBD3 PHARMA CONSULTING 100 mg/5 ml, solution à diluer pour perfusion	100mg/5ml	Concentrate for solution for infusion	Intravenous use
France	Mylan SAS 117, allée des Parcs 69800 Saint-Priest France	Iron sucrose complex	FER MYLAN 100 mg/5 ml, solution à diluer pour perfusion	100mg/5ml	Concentrate for solution for infusion	Intravenous use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	Iron sucrose complex	FER SANDOZ 100 mg/5 ml, solution à diluer pour perfusion	100mg/5ml	Concentrate for solution for infusion	Intravenous use

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France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex FRANCE	Iron sucrose complex	FER TEVA PHARMA 100 mg/5 ml, solution injectable (IV)	100mg/5ml	Solution for injection	Intravenous use
Germany	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferologic 20 mg/ml Injektionslösung/ Konzentrat zur Herstellung einer Infusionslösung	1709mg/5ml	Concentrate for solution for infusion/solution for injection	Intravenous use
Germany	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn Germany	Iron sucrose complex	FerMed	1563 - 1887mg/5ml	Concentrate for solution for infusion/solution for injection	Intravenous use
Germany	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn Germany	Iron sucrose complex	Nefro-Fer	1563 - 1887mg/5ml	Solution for injection	Intravenous use
Germany	Pharmacosmos A/S Roervangvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer 100 mg/ml Lösung zur Injektion/Infusion	377-465mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Sanofi-Aventis Deutschland GmbH Brüningstrasse 50, D-65926 Frankfurt am Main Germany	sodium ferric gluconate complex	Ferlecit 40 mg	1288.9mg/3.2 ml	Solution for injection	Intravenous use
Germany	Sanofi-Aventis Deutschland GmbH Brüningstrasse 50, D-65926 Frankfurt am Main Germany	sodium ferric gluconate complex	Ferlecit 62,5 mg	2013.9mg/5m l	Solution for injection	Intravenous use
Germany	Pharmacosmos A/S Roervangsvei 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer 50 mg/ml Injektionslösong und Infusionslösung	312.5mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Germany	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose complex	FERINJECT 50 mg Eisen/ml Injektions- und Infusionslösung	180mg/ml	Solution for injection/infusion	Intravenous use
Germany	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer 20 mg FR / ml Injektionslösung	2700mg/5ml	Concentrate for solution for infusion/solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Medicus SA Valaoritou 10 Metamorfosi Attikis 14452 Greece	Iron sucrose complex	REOXYL	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Vianex S.A. Tatoiou Street Nea Erythrea 14671 Greece	Iron sucrose complex	INTRAFER	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Alapis ABEE Aftokratoros Nikolaou 2 Athens 17671 Greece	Iron sucrose complex	FAREMIO	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Intermed ABEE Kalyftaki 27 Athens 14564 Greece	Iron sucrose complex	DEXTRIFER-S	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Demo ABEE 21ST Km National Highway Athens-Lamia, 14565 Greece	Iron (III) hydroxide dextran	COSMOFER	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Greece	Rafarm AEBE Korinthou 12, N. Psychiko, 15451 Greece	Iron sucrose complex	FERROVIN	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Nephrotech S.A. Parnithos 44 Metamorfofi Attikis 14452 Greece	Iron sucrose complex	SUCRO-FER	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Uni-Pharma Kleon Tseitis Pharmaceutical Laboratories 14KM National Highway Athens-Lamia Kifissia 14564 Greece	Iron sucrose complex	HEMAFER-S	100mg/5ml	Concentrate for solution for infusion	Intravenous use
Greece	Verisfield (UK) Ltd, U.K. 41 Chalton street London, NW1 1JD United Kingdom	Iron sucrose complex	NEPHROFEROL	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use

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Greece	HELP ABEE Valaoritou 10 Metamorfosi Attikis, 14452 Greece	Iron sucrose complex	FERRINEMIA	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	Specifar AEBE 28th October Street 1 Agia Barbara 12351 Greece	Iron sucrose complex	ALVOFER	100mg/5ml	Concentrate for solution for infusion	Intravenous use
Greece	Alet Pharmaceuticals M. Alexander 121, Agia Varvara, 12351 Greece	Iron sucrose complex	SUCROVEN	100mg/5ml	Concentrate for solution for infusion	Intravenous use
Greece	Target Pharma Ltd Menandrou 54 Athens 10431 Greece	Iron sucrose complex	IRONCROSE	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Greece	HELP ABEE Valaoritou 10 Metamorfosi Attikis, 14452 Greece	Iron (III) hydroxide dextran complex	IRONATE	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Greece	Demo ABEE 21st km National Highway Athens-Lamia, 14565 Greece	Iron(III) isomaltoside complex	MONOFER	100mg/ml	Solution for injection/infusion	Intravenous use intramuscular use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Viofar EPE Ethnikis Antistaseos & Trifyllias, Aharnai, 13671 Greece	Iron sucrose complex	VENIRON	100mg/5ml	Concentrate for solution for infusion	Intravenous use
Greece	Medicus SA Valaoritou 10 Metamorfosi Attikis 14452 Greece	Iron (III) hydroxide dextran complex	IRON (III)-HYDROXIDE DEXTRAN COMPLEX/BIOMEDIC LABORATORIES	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Hungary	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use
Hungary	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection/infusion	Intravenous use
Hungary	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Solution for injection/infusion	Intravenous use

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Hungary	Sanofi-Aventis Zrt Tó utca 1-5, 1045 Budapest Hungary	Sodium ferric gluconate complex	Ferrlecit	12.5mg/ml	Solution for injection	Intravenous use
Iceland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use
Iceland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for infusion	Intravenous use
Iceland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection	Intravenous use
Ireland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer 50mg/ml solution for infusion and injection	50mg/ml	Solution for injection/infusion	Intravenous use
Ireland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monover 100mg/ml solution for injection/infusion (ampoules)	100mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monover 100mg/ml solution for injection/infusion (vials)	100mg/ml	Solution for injection/infusion	Intravenous use
Ireland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer 20 mg iron/ml solution for injection or concentrate for solution for infusion, ampoule	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Ireland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	ferric carboxymaltose	FERINJECT 50 mg iron/ml solution for injection/infusion	50mg/ml	Solution for injection/infusion	Intravenous use
Ireland	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer 20 mg iron/ml solution for injection or concentrate for solution for infusion, vial	20mg/ml	Solution for injection/infusion	Intravenous use
Ireland	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FerroLogic 20 mg/ml solution for injection/concentrate for solution for infusion	20mg/ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	ferric carboxymaltose	FERINJECT	50mg/ml	Solution for injection/infusion	Intravenous use
Italy	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FERRO SACCARATO FME	20mg/ml	Concentrate for solution for infusion/solution for injection	Intravenous use
Italy	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER	20mg/ml	Solution for injection	Intravenous use
Italy	Sanofi-Aventis SPA Viale Luigi Bodio, 37/B 20158 Milano Italy	sodium ferric gluconate complex	FERLIXIT	62,5mg/5ml	Oral solution or solution for infusion	Oral use Intravenous use
Latvia	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection	Intravenous use
Latvia	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FerroLogic	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Latvia	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Latvia	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
Lithuania	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection	Intravenous use
Lithuania	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Lithuania	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
Lithuania	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Ferric (III) hydroxide dextran complex	CosmoFer	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Luxembourg	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Injectafer-50mg/l	50mg/ml	Solution for injection	Intravenous use
Luxembourg	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer-50mg/ml	50mg/ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn Germany	Iron sucrose complex	Fermed-100mg/5ml	100mg/5ml	Solution for perfusion	Intravenous use
Luxembourg	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferroglogic-20mg/ml	20mg/ml	Solution for perfusion	Intravenous use
Malta	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	ferric carboxymaltose	FERINJECT 50 mg iron/ml solution for injection/infusion	50mg/ml	Solution for injection/infusion	Intravenous use
Malta	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferroglogic 20 mg/ml solution for injection/concentrate for solution for infusion	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Norway	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Parenteral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Norway	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Parenteral use
Norway	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	Ferion	20mg/ml	Solution for injection Concentrate for solution for infusion	Parenteral use
Norway	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferroglogic	20mg/ml	Solution for injection Concentrate for solution for infusion	Parenteral use
Norway	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Parenteral use
Norway	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Uniferon	200mg/ml	Solution for injection	Parenteral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Norway	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection Concentrate for solution for infusion	Parenteral use
Poland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer	50mg/ml	Solution for injection/infusion	Intravenous use
Poland	VIFOR France SA 123 Rue Jules Guesde 92200 Neuilly-sur-Seine France	ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection	Intravenous use
Poland	VIFOR France SA 123 Rue Jules Guesde 92200 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection/infusion	Intravenous use
Poland	Fresenius Medical Care Nephrologica Deutschland GmbH 61346 Bad Homburg Germany	Iron sucrose complex	Ferrologic 20 mg/ml	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Poland	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl Austria	Iron(III) isomaltoside complex	Ferrum-Lek	50mg/ml	Solution for injection	Intramuscular use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monover	100mg/ml	Solution for injection/infusion	Intravenous use
Portugal	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Referen	100mg/5ml	Solution for injection	Intravenous use
Portugal	Vifor France, SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	100mg/5ml	Solution for injection	Intravenous use
Portugal	Combino Pharm Portugal, Unipessoal, Lda. Lagoas Park Edifício 8 Piso 0 2740-268 Porto Salvo Portugal	Iron sucrose complex	Óxido Férrico Sacaroso Combino	100mg/5ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Iron sucrose complex	Óxido Férrico Sacarosado Farmoz	100mg/5ml	Solution for injection	Intravenous use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Iron sucrose complex	Óxido Férrico Sacarosado Generis	100mg/5ml	Solution for injection	Intravenous use
Portugal	Laboratórios Normon, S.A. Rua Armando Villar, Lote 42 1º Dto. Quinta das Patinhas, Cobre 2750 - 777 Cascais Portugal	Iron sucrose complex	Óxido Férrico Sacarosado Normon	100mg/5ml	Solution for injection	Intravenous use
Portugal	Vifor France, SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use
Portugal	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) isomaltoside complex	Monofar	100mg/ml	Solution for injection/infusion	Intravenous use
Romania	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER®	20mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Romania	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MONOFER 100 mg/ml	100mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Romania	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	FERINJECT 50 mg fer/ml	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use
Slovak Republic	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use
Slovak Republic	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	Ferion 20 mg/ml	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic 20 mg/ml	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Slovak Republic	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection	Intravenous use
Slovenia	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic 20 mg/ml raztopina za injiciranje/ koncentrat za raztopino za infundiranje	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Slovenia	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Iroprem 50 mg/ml raztopina za iniciranje ali infundiranje	50mg/ml	Solution for injection/infusion	Intravenous use
Slovenia	Lek farmacevtska družba d.d., Verovškova 57, 1000 Ljubljana Slovenia	Iron sucrose complex	Venofer 20 mg/ml raztopina za injiciranje/ koncentrat za raztopino za infundiranje	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	COSMOFER 50 mg/ml SOLUCION PARA PERFUSION E INYECCION	50mg/ml	Solution for injection Solution for infusion	Intravenous use intramuscular use
Spain	GUERBET B.P. 57400 ROISSY CdG CEDEX F-95943 France	Iron sucrose complex	ENDOREM 11,2 mg FE/ml CONCENTRADO PARA SUSPENSION PARA PERFUSION	11,2mg/ml	Concentrate for suspension for infusion	Intravenous use
Spain	G.E.S. Genericos Espanoles Laboratorio S.A.Cólquide, 6 - Portal 2, 1 Oficina F.Las Rozas 28230 MADRID Spain	Iron sucrose complex	FERIV 20mg/ml SOLUCION INYECCABLE O CONCENTRADO PARA SOLUCION PARA PERFUSION	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Spain	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61346 Bad Homburg Germany	Iron sucrose complex	HIERRO SACAROSA FME 20 mg/ml SOLUCION INYECCABLE O CONCENTRADO PARA SOLUCION PARA PERFUSION	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Spain	Laboratorios Normon S.A. Ronda de Valdecarrizo 6 28760 Tres Cantos Madrid Spain	Iron sucrose complex	HIERRO SACAROSA NORMON 20 mg/ml SOLUCION INYECCABLE O CONCENTRADO PARA SOLUCION PARA PERFUSION	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn Germany	Iron sucrose complex	FERMED 100 mg/ 5 ml SOLUCION INYECTABLE O CONCENTRADO PARA SOLUCION PARA PERFUSION	100mg/5ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Spain	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	VENOFER 20 mg/ml SOLUCION INYECTABLE O CONCENTRADO PARA SOLUCION PARA PERFUSION	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
Spain	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	FERINJECT 50 mg/ml SOLUCION INYECTABLE Y PARA PERFUSION	50mg/ml	Solution for injection Solution for infusion	Intravenous use
Spain	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MONOFERRO 100 mg/ml SOLUCIÓN INYECTABLE O PARA PERFUSIÓN	100mg/ml	Solution for injection Solution for infusion	Intravenous use
Sweden	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Iron sucrose complex	Venofer®	20mg/ml	Concentrate for solution for injection	Intravenous use
Sweden	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer®	50mg/ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Sweden	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92200 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection	Intravenous use
Sweden	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61346 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Concentrate for solution for injection	Intravenous use
Sweden	Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland	Iron sucrose complex	Ferion	20mg/ml	Concentrate for solution for injection	Intravenous use
Sweden	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MonoFer®	100mg/ml	Solution for injection	Intravenous use
The Netherlands	Pharmamatch B.V. Egelenburg 2 Amsterdam GK - 1081 The Netherlands	Iron sucrose complex	IJzerhydroxide sacharose complex bevattende 20 mg/ml IJzer PHARMAMATCH, oplossing/concentraat voor oplossing voor injectie	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	FerroLogic 20 mg/ml, oplossing voor injectie of concentraat voor oplossing voor infusie	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
The Netherlands	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	MonoFer 100 mg/ml oplossing voor injectie/infusie	100mg/ml	Solution for injection/infusion	Intravenous use
The Netherlands	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer 20 mg/ml ijzer (III), oplossing voor injectie of concentraat voor oplossing voor intraveneuze infusie	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
The Netherlands	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	FERINJECT 50 mg ijzer/ ml, oplossing voor injectie/infusie	50mg/ml	Solution for injection/infusion	Intravenous use
The Netherlands	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	CosmoFer 50 mg/ml oplossing voor infusie en injectie	50mg/ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Pharmachemie B.V. Haarlem - 2031 GA The Netherlands	Iron sucrose complex	IJzerhydroxide sacharose complex 20 mg/ml PCH, oplossing voor injectie/concentraat voor oplossing voor infusie	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
United Kingdom	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Iron sucrose complex	Venofer	20mg/ml	Solution for injection/infusion	Intravenous use
United Kingdom	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Monofer	100mg/ml	Solution for injection/infusion	Intravenous use
United Kingdom	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron(III) isomaltoside complex	Diafer	50mg/ml	Solution for injection	Intravenous use
United Kingdom	Pharmacosmos A/S Roervangsvej 30 Holbaek DK-4300 Denmark	Iron (III) hydroxide dextran complex	Cosmofer	50mg/ml	Solution for injection/infusion	Intravenous use intramuscular use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Fresenius Medical Care Nephrologica Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg Germany	Iron sucrose complex	Ferrologic	20mg/ml	Solution for injection Concentrate for solution for infusion	Intravenous use
United Kingdom	VIFOR France SA 7-13 Boulevard Paul Emile Victor 92521 Neuilly-sur-Seine France	Ferric carboxymaltose	Ferinject	50mg/ml	Solution for injection/infusion	Intravenous use