

29 November 2017  
EMA/5041/2014 corr.5\*  
Patient Health Protection

List of intravenous iron-containing medicinal products in the EU

Name of the product	Marketing Authorisation Holder	Country where product is authorised
CosmoFer 50 mg/ml Injektionslösung und Infusionslösung	Pharmacosmos A/S	Austria
Ferinject 50 mg Eisen/ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	VIFOR France SA	Austria
FerMed 100 mg/5 ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	Medice Arzneimittel Pütter GmbH & Co KG	Austria
Ferroloac 20 mg/ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	Fresenius Medical Care Nephrologica Deutschland GmbH	Austria
Monofer 100 mg/ml Injektions- oder Infusionslösung	Pharmacosmos A/S	Austria
Venofer 20 mg/ml - Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	VIFOR France SA	Austria
Cosmofer	Pharmacosmos A/S	Belgium
Monover	Pharmacosmos A/S	Belgium
Venofer	VIFOR France SA	Belgium
Injectafer	VIFOR France SA	Belgium
Ferinject	VIFOR France SA	Bulgaria
Idafer	Pharmaloq AG	Bulgaria
Cosmofer	Pharmacosmos A/S	Bulgaria
Monofer	Pharmacosmos A/S	Bulgaria
Ferinject Solution for Injection or Infusion 50 mg Iron/ml	VIFOR France SA	Cyprus
Monofer Solution for Injection or Infusion 100 mg/ml	Pharmacosmos A/S	Cyprus
Cosmofer Solution for Injection or Infusion 50 mg Iron/ml	Pharmacosmos A/S	Cyprus
Venofer Injection 100 mg Iron/5 ml	The Star Medicines Importers & Co Ltd	Cyprus
Ferroloac Solution for Injection/Concentrate for Solution for Infusion 20 mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Cyprus
Venofer	VIFOR France SA	Czech Republic
Ferroloac 20 mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Czech Republic
Iron Sucrose Pharmabide 20 mg/ml	Pharmabide Ltd	Czech Republic
Ferion 20 mg/ml	Orion Corporation	Czech Republic
Ferilecit	Sanofi-Aventis, s.r.o.	Czech Republic
Ferinject	VIFOR France SA	Czech Republic
Cosmofer	Pharmacosmos A/S	Denmark
Ferinject	VIFOR France SA	Denmark
Ferion	Orion Corporation	Denmark
Ferroloac	Fresenius Medical Care Nephrologica Deutschland GmbH	Denmark
Jerndextran "Pharmacosmos"	Pharmacosmos A/S	Denmark
MonoFer	Pharmacosmos A/S	Denmark
Venofer	VIFOR France SA	Denmark
Venofer	VIFOR France SA	Estonia
Ferroloac 20mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Estonia
Ferion	Orion Corporation	Estonia
Cosmofer	Pharmacosmos A/S	Estonia

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Monofer	Pharmacosmos A/S	Estonia
Ferrum Lek	Lek Pharmaceuticals d.d.	Estonia
Ferinject	VIFOR France SA	Finland
Ferrolagic	Fresenius Medical Care Nephrologica Deutschland GmbH	Finland
Venofer	VIFOR France SA	Finland
Venotrix	Alternova A/S	Finland
Cosmofer	Pharmacosmos A/S	Finland
Monofer	Pharmacosmos A/S	Finland
Ferinject 50 mg/ml, solution injectable/pour perfusion	VIFOR France SA	France
Venofer 20 mg/ml, solution injectable	VIFOR France SA	France
Ferrisat 50 mg/ml, solution injectable ou pour perfusion	Pharmacosmos A/S	France
Fer Actavis 100 mg/5 ml, solution injectable	Pharmaki Generics Ltd	France
FER PANPHARMA 100 mg/5 ml, solution à diluer pour perfusion	PANMEDICA	France
Fer Mylan 100 mg/5 ml, solution à diluer pour perfusion	Mylan SAS	France
Fer Sandoz 100 mg/5 ml, solution à diluer pour perfusion	SANDOZ	France
Fer Teva Pharma 100 mg/5 ml, solution injectable (IV)	TEVA SANTE	France
Ferrolagic 20 mg/ml Injektionslösung/ Konzentrat zur Herstellung einer Infusionslösung	Fresenius Medical Care Nephrologica Deutschland GmbH	Germany
FerMed	Medice Arzneimittel Pütter GmbH & Co KG	Germany
Nefro-Fer	Medice Arzneimittel Pütter GmbH & Co KG	Germany
Monofer 100 mg/ml Lösung zur Injektion/Infusion	Pharmacosmos A/S	Germany
Ferrlecit 40 mg	Sanofi-Aventis Deutschland GmbH	Germany
Ferrlecit 62,5 mg	Sanofi-Aventis Deutschland GmbH	Germany
Cosmofer 50 mg/ml Injektionslösung und Infusionslösung	Pharmacosmos A/S	Germany
Ferinject 50 mg Eisen/ml Injektions- und Infusionslösung	VIFOR France SA	Germany
Venofer 20 mg FR / ml Injektionslösung	VIFOR France SA	Germany
Reoxyl	Medicus SA	Greece
Intrafer	Vianex S.A.	Greece
Faremo	Alapis ABEE	Greece
Dextrifer-S	Intermed ABEE	Greece
Venofer	VIFOR France SA	Greece
Cosmofer	Demo ABEE	Greece
Ferrovin	Rafarm AEBE	Greece
Sucro-Fer	Nephrotech S.A.	Greece
Hemafer-S	Uni-Pharma Kleon Tseltis	Greece
Nephroferol	Verisfield (UK) Ltd, U.K.	Greece
Ferrinemia	HELP ABEE	Greece
Alvofer	Specifar AEBE	Greece
Sucroven	Alet Pharmaceuticals	Greece
Ironcrose	Target Pharma Ltd	Greece
Ironate	HELP ABEE	Greece
Monofer	Demo ABEE	Greece

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Veniron	Viofar EPE	Greece
Iron (III)-Hydroxide Dextran Complex/Biomedic Laboratories	Medicus SA	Greece
Ferinject	VIFOR France SA	Hungary
Venofer	VIFOR France SA	Hungary
Ferrologic	Fresenius Medical Care Nephrologica Deutschland GmbH	Hungary
Ferrlecit	Sanofi-Aventis Zrt	Hungary
Ferinject	VIFOR France SA	Iceland
Monofer	Pharmacosmos A/S	Iceland
Venofer	VIFOR France SA	Iceland
CosmoFer 50mg/ml solution for infusion and injection	Pharmacosmos A/S	Ireland
Monover 100mg/ml solution for injection/infusion (ampoules)	Pharmacosmos A/S	Ireland
Monover 100mg/ml solution for injection/infusion (vials)	Pharmacosmos A/S	Ireland
Venofer 20 mg iron/ml solution for injection or concentrate for solution for infusion, ampoule	VIFOR France SA	Ireland
Ferinject 50 mg iron/ml solution for injection/infusion	VIFOR France SA	Ireland
Venofer 20 mg iron/ml solution for injection or concentrate for solution for infusion, vial	VIFOR France SA	Ireland
FerroLogic 20 mg/ml solution for injection/concentrate for solution for infusion	Fresenius Medical Care Nephrologica Deutschland GmbH	Ireland
Ferinject	VIFOR France SA	Italy
Ferro Saccarato FME	Fresenius Medical Care Nephrologica Deutschland GmbH	Italy
Venofer	VIFOR France SA	Italy
Ferlixit	Sanofi-Aventis SPA	Italy
Ferinject	VIFOR France SA	Latvia
Venofer	VIFOR France SA	Latvia
CosmoFer	Pharmacosmos A/S	Latvia
Monofer	Pharmacosmos A/S	Latvia
Ferinject	VIFOR France SA	Lithuania
Venofer	VIFOR France SA	Lithuania
Ferrologic	Fresenius Medical Care Nephrologica Deutschland GmbH	Lithuania
Monofer	Pharmacosmos A/S	Lithuania
CosmoFer	Pharmacosmos A/S	Lithuania
Injectafer -50mg/l	VIFOR France SA	Luxembourg
Cosmofer-50mg/ml	Pharmacosmos A/S	Luxembourg
Fermed-100mg/5ml	Medice Arzneimittel Putter GmbH & Co KG	Luxembourg
Ferrologic-20mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Luxembourg
Ferinject 50 mg iron/ml solution for injection/infusion	VIFOR France SA	Malta
Ferrologic 20 mg/ml solution for injection/concentrate for solution for infusion	Fresenius Medical Care Nephrologica Deutschland GmbH	Malta
Cosmofer	Pharmacosmos A/S	Norway
Ferinject	VIFOR France SA	Norway
Ferion	Orion Corporation	Norway
Ferrologic	Fresenius Medical Care Nephrologica Deutschland GmbH	Norway
Monofer	Pharmacosmos A/S	Norway
Uniferon	Pharmacosmos A/S	Norway

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Venofer	VIFOR France SA	Norway
Cosmofer	Pharmacosmos A/S	Poland
Ferinject	VIFOR France SA	Poland
Venofer	VIFOR France SA	Poland
Ferroloic 20 mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Poland
Ferrum-Lek	Sandoz GmbH	Poland
Monover	Pharmacosmos A/S	Poland
Referen	Fresenius Medical Care Nephrologica Deutschland GmbH	Portugal
Venofer	VIFOR France SA	Portugal
Oxido Férnico Sacarosado Combino	Combino Pharm Portugal, Unipessoal, Lda.	Portugal
Oxido Férnico Sacarosado Generis	Generis Farmacéutica, S.A.	Portugal
Ferinject	VIFOR France SA	Portugal
Cosmofer	Pharmacosmos A/S	Portugal
Monofar	Pharmacosmos A/S	Portugal
Venofer®	VIFOR France SA	Romania
Monofer 100 mg/ml	Pharmacosmos A/S	Romania
Ferinject 50 mg fer/ml	VIFOR France SA	Romania
Ferinject	VIFOR France SA	Slovak Republic
Ferion 20 mg/ml	Orion Corporation	Slovak Republic
Ferroloic 20 mg/ml	Fresenius Medical Care Nephrologica Deutschland GmbH	Slovak Republic
Venofer	VIFOR France SA	Slovak Republic
Ferroloic 20 mg/ml raztopina za injiciranje/ koncentrat za raztopino za infundiranje	Fresenius Medical Care Nephrologica Deutschland GmbH	Slovenia
Iroprem 50 mg/ml raztopina za injiciranje ali infundiranje	VIFOR France SA	Slovenia
Venofer 20 mg/ml raztopina za injiciranje/ koncentrat za raztopino za infundiranje	Lek farmacevtska družba d.d.	Slovenia
Cosmofer 50 mg/ml solución para perfusión e inyección	Pharmacosmos A/S	Spain
Feriv 20mg/ml solución inyectable o concentrado para solución para perfusión	G.E.S. Genericos Espanoles Laboratorio	Spain
Hierro Sacarosa Normon 20 mg/ml solución inyectable o concentrado para solución para perfusión	Laboratorios Normon S.A.	Spain
Venofer 20 mg/ml solución inyectable o concentrado para solución para perfusión	VIFOR France SA	Spain
Ferinject 50 mg/ml solución inyectable y para perfusión	VIFOR France SA	Spain
Monoferro 100 mg/ml solución inyectable o para perfusión	Pharmacosmos A/S	Spain
Venofer®	VIFOR France SA	Sweden
Cosmofer®	Pharmacosmos A/S	Sweden
Ferinject	VIFOR France SA	Sweden
Ferroloic	Fresenius Medical Care Nephrologica Deutschland GmbH	Sweden
Ferion	Orion Corporation	Sweden
MonoFer®	Pharmacosmos A/S	Sweden
IJzerhydroxide sacharose complex bevattende 20 mg/ml IJzer PHARMAMATCH, oplossing/concentraat voor oplossing voor injectie	Pharmamatch B.V.	The Netherlands
FerroLoic 20 mg/ml, oplossing voor injectie of concentraat voor oplossing voor infusie	Fresenius Medical Care Nephrologica Deutschland GmbH	The Netherlands
MonoFer 100 mg/ml oplossing voor injectie/infusie	Pharmacosmos A/S	The Netherlands
Venofer 20 mg/ml ijzer (III), oplossing voor injectie of concentraat voor oplossing voor intraveneuze infusie	VIFOR France SA	The Netherlands
Ferinject 50 mg IJzer/ml, oplossing voor injectie/infusie	VIFOR France SA	The Netherlands

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CosmoFer 50 mg/ml oplossing voor infusie en injectie	Pharmacosmos A/S	The Netherlands
IJzerhydroxide sacharose complex 20 mg/ml PCH, oplossing voor injectie/concentraat voor oplossing voor infusie	Pharmachemie B.V.	The Netherlands
<b>Ferracin oplossing voor injectie/concentraat voor oplossing voor infusie **</b>	<b>Acino AG</b>	<b>The Netherlands</b>
Venofer	VIFOR France SA	United Kingdom
Monofer	Pharmacosmos A/S	United Kingdom
Diafer	Pharmacosmos A/S	United Kingdom
Cosmofer	Pharmacosmos A/S	United Kingdom
Ferroloac	Fresenius Medical Care Neohrologica Deutschland GmbH	United Kingdom
Ferinject	VIFOR France SA	United Kingdom

\* This annex was previously amended on 27/09/2017.

\*\* The MAH of Ferracin oplossing voor injectie/concentraat voor oplossing voor infusie is part of the Iron MAHs Consortium which are performing a joint PASS as an outcome of the article 31 referral procedure on Intravenous iron-containing medicinal products finalised in 2013.