



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/607374/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: intravenous iron

Procedure no.: EMEA/H/N/PSR/J/0026

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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
Cosmofer	DK/H/0169/01	1-24166	Pharmacosmos A/S	AT
Cosmofer	National	20070017	Pharmacosmos A/S	BG
Cosmofer	DK/H/0169/01	50230.00.00	Pharmacosmos A/S	DE
Cosmofer	DK/H/0169/01	30495	Pharmacosmos A/S	DK
Cosmofer	DK/H/0169/01	521606	Pharmacosmos A/S	EE
Cosmofer	DK/H/0169/01	2498901	Pharmacosmos A/S	EL
Cosmofer	DK/H/0169/01	68243	Pharmacosmos A/S	ES
Cosmofer	DK/H/0169/01	PA982/001/001	Pharmacosmos A/S	IE
Cosmofer	DK/H/0169/01	LT/1/06/0678/001-005	Pharmacosmos A/S	LT

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Cosmofer	DK/H/0169/01	No.AM 1304/01070003	Pharmacosmos A/S	LU
Cosmofer	DK/H/0169/01	Reg. no. 07-0132	Pharmacosmos A/S	LV
Cosmofer	DK/H/0169/01	RVG 25702	Pharmacosmos A/S	NL
Cosmofer	DK/H/0169/01	MTnr. 00-4650	Pharmacosmos A/S	NO
Cosmofer	National	10630	Pharmacosmos A/S	PL
Cosmofer	DK/H/0169/01	5882881	Pharmacosmos A/S	PT
Cosmofer	DK/H/0169/01	23462	Pharmacosmos A/S	SE
Cosmofer	DK/H/0169/01	PL 18380/0002- 0001	Pharmacosmos A/S	UK
Eisen Sucrose Baxter 20 mg Iron/ mL Solution for Injection /Infusion	DE/H/6316/001 /DC	98524.00.00	Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, NL	DE

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Fer Arrow 100mg/5ml, solution injectable	Not applicable	NL37737	Arrow Génériques	FR
FER BAXTER 20 mg Iron/ mL Solution for Injection /Infusion	DE/H/6316/001 /DC	NL47525	Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, NL	France
FER PANPHARMA 100 mg/5 ml, solution à diluer pour perfusion	Not applicable: National MA	NL 38340: 34009 580 046 1 2: Boîte de 1. 34009 580 047 8 0: Boîte de 5. 34009 580 048 4 1: Boîte de 10. 34009 580 049 0 2: Boîte de 20.	PANMEDICA	FR
FER SANDOZ 100 mg/5 ml, solution à diluer pour perfusion	National	34009 573 473 5 2	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	FR
FERCAYL 100mg/2ml, solution for injection/infusion	National	BE168497	Laboratoires Sterop NV	BE
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	66227.00.00	Vifor France	DE
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	21204/25-02-2019	Vifor France	EL

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
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	69771	Vifor France	ES
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	OGYI-T-21344/01 (1x2ml); OGYI-T-21344/02 (5x2ml); OGYI-T-21344/03 (1x10ml); OGYI-T-21344/04 (5x10ml); OGYI-T-21344/05 (1x20ml)	Vifor France	HU
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	1308/10110018	Vifor France	LU
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	08-0017	Vifor France	LV
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	RVG33865	Vifor France	NL
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	09-7172	Vifor France	NO
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	16248	Vifor France	PL
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	5242268 (1x2ml); 5047279 (5x2ml); 5242250 (1x10ml); 5047303 (5x10ml); 5588751 (1x20ml)	Vifor France	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	5232/2012/01 (1x2ml); 5232/2012/02 (2x2ml); 5232/2012/03 (5x2ml); 5232/2012/04 (1x10ml); 5232/2012/05 (2x10ml); 5232/2012/06 (5x10ml); 5232/2012/07 (1x20ml)	Vifor France	RO
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	23738	Vifor France	SE
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	H/10/01915/001 (1x2 ml); H/10/01915/003 (2x2 ml); H/10/01915/002 (5x2 ml); H/10/01915/004 (1x10 ml); H/10/01915/005 (2x10 ml); H/10/01915/006 (5x10 ml); H/10/01915/007 (1x20 ml)	Vifor France	SI
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/001	PL 15240/0002	Vifor France	UK
Ferinject 50 mg/ml solution For injection/infusion	SE/H/1816/001	34009 386 812 4 6 (1x2ml); 34009 386 823 6 6 (5x2ml); 34009 386 924 7 1 (1x10ml); 34009 386 933 6 2 (5x10ml); 34009 219 393 1 6 (2x2ml);	Vifor France	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
		34009 219 394 8 4 (2x10ml);		
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	PA0949/004/001	Vifor France	IE
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	IS/1/10/042/01	Vifor France	IS
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	040251011(1x2ml); 040251023(5x2ml); 040251035(1x10ml); ; 040251047(5x10ml); ; 040251074 (1x20ml)	Vifor France	IT
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	12/747/07-C	Vifor France	CZ
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	12/0250/07-S	Vifor France	SK
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	1-27299	Vifor France	AT
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	BE371393 (2ml); BE371402 (10ml); BE452711 (20ml)	Vifor France	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
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	20100482	Vifor France	BG
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	20795	Vifor France	CY
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	39254	Vifor France	DK
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	556607	Vifor France	EE
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	22144	Vifor France	FI
Ferinject 50 mg/ml solution for injection/infusion	SE/H/1816/00 1	HR-H-646532651-01 (1x2ml); HR-H-646532651-02 (2x2ml); HR-H-646532651-03 (5x2ml); HR-H-646532651-04 (1x10ml); HR-H-646532651-05 (2x10ml); HR-H-646532651-06 (5x10ml); HR-H-646532651-07 (1x20ml);	Vifor France	HR
FERIV 20mg/ml SOLUCION INYECTABLE O		66705	G.E.S. GENERICOS ESPAÑOL ES LABORATORIO, S.A.	ES

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
CONCENTRADO PARA SOLUCION PARA PERFUSION				
Ferlixit 62,5 mg/5 ml, solution for oral use and intravenous use	Not applicable	021455023	Sanofi S.p.A.	IT
FerMed	DE/H/1448/00 1	1-28603	Medice Arzneimittel Pütter GmbH & Co. KG	AT
FerMed	National	71610.00.00	Medice Arzneimittel Pütter GmbH & Co. KG	DE
FerMed	DE/H/1448/00 1	1754/1010000 8	Medice Arzneimittel Pütter GmbH & Co. KG	LU
FerMylan 100 mg/5ml, solution à diluer pour perfusion	Not applicable	NL34669	Mylan S.A.S.	FR
Ferracin oplossing voor injectie/concentra at voor oplossing voor infusie	Not applicable - authorised through national procedure (RVG112056)	RVG 112056	Acino AG	NL
Ferrlecit 12,5 mg/ml oldatos injekció, Solution for injection/infusion	Not applicable	OGYI-T-438/01	Sanofi-Aventis Zrt	HU
Ferrlecit 12.5mg/ml, Solution for injection/infusion	Not applicable	12/174/73/-C	sanofi-aventis, s.r.o.	CZ

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
Ferrlecit 40 mg, Solution for injection or concentrate for solution for infusion	Not applicable	6441686.00.00	Sanofi-Aventis Deutschland GmbH	DE
Ferrlecit 62,5 mg, Solution for injection or concentrate for solution for infusion	Not applicable	6385744.00.00	Sanofi-Aventis Deutschland GmbH	DE
FERROVIN 20 mg iron / ml, solution for injection or concentrate for solution for infusion	N/A	021660	RAFARM SA	CY
FERROVIN 20 mg iron / ml, solution for injection or concentrate for solution for infusion	N/A	96896/13/3-2-2016	RAFARM SA	EL
FERROVIN 20 mg iron / ml, solution for injection or concentrate for solution for infusion	N/A	AA214/01301	RAFARM SA	MT
Idafer	National	20020040	Vifor France	BG
IJzerhydroxide sacharose complex Teva 20 mg/ml, oplossing voor injectie/concentra at voor oplossing	Not applicable	RVG 33727	Pharmachemie B.V.; Swensweg 5, 2031 GA, Haarlem	NL

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
voor infusie				
Monofar	SE/H/734/01	5268172, 5268206, 5268214	Pharmacosmos A/S	PT
Monofer	SE/H/734/01	1-29203	Pharmacosmos A/S	AT
Monofer	SE/H/734/01	20100378	Pharmacosmos A/S	BG
Monofer	SE/H/734/01	75060.00.00	Pharmacosmos A/S	DE
Monofer	SE/H/734/01	MT Nr. 43747	Pharmacosmos A/S	DK
Monofer	SE/H/734/01	72364/25-10-2010	Pharmacosmos A/S	EL
Monofer	SE/H/734/01	671910	Pharmacosmos A/S	ET
Monofer	SE/H/734/01	25286	Pharmacosmos A/S	FI

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Monofer	National	UP/I-530-09/12- 01/567	Pharmacosmos A/S	HR
Monofer	SE/H/734/01	IS/1/09/010/01	Pharmacosmos A/S	IS
Monofer	SE/H/734/01	LT/1/10/1898/001- 008	Pharmacosmos A/S	LT
Monofer	SE/H/734/01	10-0203-0206	Pharmacosmos A/S	LV
Monofer	SE/H/734/01	RVG 103070	Pharmacosmos A/S	NL
Monofer	SE/H/734/01	08-6145	Pharmacosmos A/S	NO
Monofer	SE/H/734/01	2389/2010/01/01-16	Pharmacosmos A/S	RO
Monofer	SE/H/734/01	SE27791	Pharmacosmos A/S	SE
Monofer	SE/H/734/01	PL 18380/0001 - 0001	Pharmacosmos A/S	UK

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Monoferro	SE/H/734/01	72381	Pharmacosmos A/S	ES
Monover	National	NL 40157 (34009 550 201 6 5 - 34009 550 204 3 1)	Pharmacosmos A/S	FR
Monover	SE/H/734/01	PA0982/002/001-002	Pharmacosmos A/S	IE
Monover	SE/H/734/01	2012030052	Pharmacosmos A/S	LU
Monover	SE/H/734/01	16535	Pharmacosmos A/S	PL
NefroFer	DE/H/1448/00 1	71717.00.00	Medice Arzneimittel Pütter GmbH & Co. KG	DE
Óxido Férrico Sacarosado Accord 100 mg/ 5 ml Solução injetável		5140447 (Ampola - 10 unidade(s) - 5 ml)	Accord Healthcare Limited	PT
Óxido Férrico Sacarosado Accord 100 mg/ 5 ml Solução injetável		5140421 (Ampola - 1 unidade(s) - 5 ml)	Accord Healthcare Limited	PT
Óxido Férrico Sacarosado Accord 100 mg/ 5 ml Solução injetável		5140439 (Ampola - 5 unidade(s) - 5 ml)	Accord Healthcare Limited	PT

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Óxido Férrico Sacarosado Generis	5037015; 5037007; 5036975	06/H/0238/00 1	Generis Farmacêutica S.A.	PT
Sucrofer20 mg Iron/ mL Solution for Injection /Infusion	DE/H/6316/001 /DC	PL 00116/0690	Baxter Healthcare Limited Caxton Way Thetford, Norfolk IP24 3SE	UK
Venofer	SE/H/1842/001	1-23754	Vifor France	AT
Venofer	SE/H/1842/001	BE 216492 (5 ml Amp); BE 345502 (5 ml vials; BE 459555 (2.5ml vials)	Vifor France	BE
Venofer	National	14320	The Star Medicines Importers Co Ltd	CY
Venofer	National	12/051/04-C	Vifor France	CZ
Venofer	National	6462062.00.00	Vifor France	DE
Venofer	SE/H/1842/001	31111	Vifor France	DK
Venofer	National	454104	Vifor France	EE

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Venofer	SE/H/1842/001	107446/24-09-2019	Vifor France	EL
Venofer	SE/H/1842/001	64000	Vifor France	ES
Venofer	SE/H/1842/001	14727	Vifor France	FI
Venofer	National	340095618963 2 (5ml ampoules); 340095712834 0 (5ml vials); 340095791526 1 (2.5ml vials)	Vifor France	FR
Venofer	National	OGYI-T- 6362/01	Vifor France	HU
Venofer	SE/H/1842/001	PA0949/001/0 01 (5ml ampoules) PA0949/001/0 02 (5 and 2.5ml vials)	Vifor France	IE
Venofer	National	IS/1/01/063/0 1	Vifor France	IS
Venofer	SE/H/1842/001	035283011 (5 ml ampoules) 035283023 (5 ml vials); 035283035 (2.5 ml vials)	Vifor France	IT
Venofer	National	LT/1/04/0097/ 001	Vifor France	LT

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Venofer	SE/H/1842/001	2001070069	Vifor France	LU
Venofer	National	98-0243	Vifor France	LV
Venofer	National	RVG 20690	Vifor France	NL
Venofer	National	99-4553	Vifor France	NO
Venofer	National	R/1920	Vifor France	PL
Venofer	National	8109603 (5ml ampoules); 5450176 (5 ml vials)	Vifor France	PT
Venofer	National	10726/2018/01 (5ml ampoules) 10726/2018-01-02 (5ml vials)	Vifor France	RO
Venofer	SE/H/1842/001	15754	Vifor France	SE
Venofer	National	12/0852/92-S	Vifor France	SK

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Venofer	SE/H/1842/001	PL 15240/0001	Vifor France	UK
Venofer 20 mg/ml otopina za injekciju/infuziju	National	HR-H- 398921872	Sandoz d.o.o., HR	HR
Venofer 20 mg/ml raztopina za injiciranje/koncentrat za raztopino za infundiranje	National	H/98/02040/0 01	LEK Pharmaceutic als d.d. SI	SI
Venotrix 20 mg/ml injektioneste, liuos/infuusiokonsentraatti, liuosta varten	Not applicable - authorised through national procedure	21590	Orifarm Generics A/S (Alternova A/S)	FI