



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 January 2020  
EMA/143053/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: human hemin

Procedure no.: PSUSA/00001629/201905

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Normosang 25 mg/ml, concentrate for solution for infusion	FR/H/0140/001	PL 15266/0008	RECORDATI RARE DISEASES	UK
Normosang 25 mg/ml, concentraat voor oplossing voor infusie	FR/H/0140/001	RVG 33614	RECORDATI RARE DISEASES	NL
NORMOSANG 25 mg/ml, concentrado para solución para perfusión.	FR/H/0140/001	63.116	RECORDATI RARE DISEASES	ES
Normosang 25 mg/ml, concentrado para solução para perfusão	FR/H/0140/001	2938082	RECORDATI RARE DISEASES	PT
Human Hemin Orphan Europe 25 mg/ml, koncentrat do sporządzania roztworu do infuzji	FR/H/0140/001	12612	ORPHAN EUROPE SARL	PL
Normosang 25 mg/ml – infuusiokonsentraatti liuosta varten	FR/H/0140/001	21924	RECORDATI RARE DISEASES	FI
Normosang 25 mg/ml, concentraat voor oplossing voor infusie	FR/H/0140/001	BE207496	RECORDATI RARE DISEASES	BE
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	0084/99/07/0010	RECORDATI RARE DISEASES	LU

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	BE207496	RECORDATI RARE DISEASES	BE
Normosang 25 mg/ml, solution à diluer pour perfusion	FR/H/0140/001	BE207496	RECORDATI RARE DISEASES	BE
Normosang 25 mg/ml konzentrat za otopinu za infuziju	not available	HR-H-963951477	ORPHAN EUROPE SARL	HR
Normosang 25 mg/ml konzentrat za raztopino za infundiranje	FR/H/0140/001	H/09/01129/001	RECORDATI RARE DISEASES	SI
NORMOSANG 25 mg/ml, concentrate for solution for infusion	FR/H/140/01	PA928/1/1	RECORDATI RARE DISEASES	IE
Normosang 25 mg/ml, konsentrat til infusjonsvæske, oppløsning	FR/H/0140/001	06-3943	RECORDATI RARE DISEASES	NO
Normosang 25 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	1-27260	RECORDATI RARE DISEASES	AT
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	PEI.H.03381.01.1	RECORDATI RARE DISEASES	DE

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Normosang, konzentrat til infusionsvæske, opløsning	FR/H/0140/001	30617	RECORDATI RARE DISEASES	DK
Normosang 25 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	FR/H/0140/001	18966/22-10-99	RECORDATI RARE DISEASES	GR
Normosang 25 mg/ml infusioonilahuse kontsentraat	FR/H/0140/001	524806	RECORDATI RARE DISEASES	EE
Normosang 25 mg/ml, solution à diluer pour perfusion	FR/H/0140/001	34009 558 611 1 9	RECORDATI RARE DISEASES	FR
Normosang 25 mg/ml koncentrátum oldatos infúzióhoz	FR/H/0140/001	OGYI-T-20408/01	RECORDATI RARE DISEASES	HU
Normosang 25 mg/ml innrennslisþykkni, lausn	FR/H/0140/001	IS/1/06/015/01	RECORDATI RARE DISEASES	IS
Normosang 25 mg/ml, koncentrát pro infuzní roztok	FR/H/0140/001	80/271/06-C	RECORDATI RARE DISEASES	CZ
Normosang 25 mg/mL, concentrato per soluzione per infusione	FR/H/0140/001	034543013/M	RECORDATI RARE DISEASES	IT
Normosang 25 mg/ml koncentratas infuziniam tirpalui	FR/H/0140/001	LT/1/08/1024/001	RECORDATI RARE DISEASES	LT

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
NORMOSANG 25 mg/ml koncentrāts infūziju šķīduma pagatavošanai	FR/H/0140/001	06-0218	RECORDATI RARE DISEASES	LV
Normosang 25 mg/ml, koncentrat għal soluzzjoni għall-infuzjoni	FR/H/0140/001	MA135/00101	RECORDATI RARE DISEASES	MT
Normosang 25 mg/ml, koncentrat till infusionsvätska, lösning	FR/H/0140/001	15349	RECORDATI RARE DISEASES	SE
NORMOSANG 25 mg/ml infúzný koncentrát	FR/H/0140/001	80/0348/09-S	RECORDATI RARE DISEASES	SK
Normosang 25 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση.	FR/H/140/01	18966	RECORDATI RARE DISEASES	CY