



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/31860/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: human hemin

Procedure no.: PSUSA/00001629/201805



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
Normosang 25 mg/ml, concentrate for solution for infusion	FR/H/0140/001	PL 15266/0008	ORPHAN EUROPE SARL	UK
Normosang 25 mg/ml, concentraat voor oplossing voor infusie	FR/H/0140/001	RVG 33614	ORPHAN EUROPE SARL	NL
NORMOSANG 25 mg/ml, concentrado para solución para perfusión.	FR/H/0140/001	63.116	ORPHAN EUROPE SARL	ES
Normosang 25 mg/ml, concentrado para solução para perfusão	FR/H/0140/001	2938082	ORPHAN EUROPE SARL	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	ORPHAN EUROPE SARL	FI
Normosang 25 mg/ml, concentraat voor oplossing voor infusie	FR/H/0140/001	BE207496	ORPHAN EUROPE SARL	BE
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	0084/99/07/0010	ORPHAN EUROPE SARL	LU
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	BE207496	ORPHAN EUROPE SARL	BE
Normosang 25 mg/ml, solution à diluer pour perfusion	FR/H/0140/001	BE207496	ORPHAN EUROPE SARL	BE
Normosang 25 mg/ml	not available	HR-H-963951477	ORPHAN EUROPE SARL	HR

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koncentrat za otopinu za infuziju				
Normosang 25 mg/ml koncentrat za raztopino za infundiranje	FR/H/0140/001	H/09/01129/001	ORPHAN EUROPE SARL	SI
NORMOSANG 25 mg/ml, concentrate for solution for infusion	FR/H/140/01	PA928/1/1	ORPHAN EUROPE SARL	IE
Normosang 25 mg/ml, konsentrat til infusionsvæske, opløsning	FR/H/0140/001	06-3943	ORPHAN EUROPE SARL	NO
Normosang 25 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	1-27260	ORPHAN EUROPE SARL	AT
Normosang 25 mg/ml, Konzentrat zur Herstellung einer Infusionslösung	FR/H/0140/001	PEI.H.03381.01.1	ORPHAN EUROPE SARL	DE
Normosang, koncentrat til infusionsvæske, opløsning	FR/H/0140/001	30617	ORPHAN EUROPE SARL	DK
Normosang 25 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	FR/H/0140/001	18966/22-10-99	ORPHAN EUROPE SARL	GR
Normosang 25 mg/ml infusioonilahuse kontsentraat	FR/H/0140/001	524806	ORPHAN EUROPE SARL	EE
Normosang 25 mg/ml, solution à diluer pour perfusion	FR/H/0140/001	34009 558 611 1 9	ORPHAN EUROPE SARL	FR
Normosang 25 mg/ml koncentrátum oldatos	FR/H/0140/001	OGYI-T-20408/01	ORPHAN EUROPE SARL	HU

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infúzióhoz				
Normosang 25 mg/ml innrennslisþykkni, lausn	FR/H/0140/001	IS/1/06/015/01	ORPHAN EUROPE SARL	IS
Normosang 25 mg/ml, koncentrát pro infuzní roztok	FR/H/0140/001	80/271/06-C	ORPHAN EUROPE SARL	CZ
Normosang 25 mg/mL, concentrato per soluzione per infusione	FR/H/0140/001	034543013/M	ORPHAN EUROPE SARL	IT
Normosang 25 mg/ml koncentratas infuziniam tirpalui	FR/H/0140/001	LT/1/08/1024/001	ORPHAN EUROPE SARL	LT
NORMOSANG 25 mg/ml koncentrāts infūziju šķīduma pagatavošanai	FR/H/0140/001	06-0218	ORPHAN EUROPE SARL	LV
Normosang 25 mg/ml, koncentrat għal soluzzjoni għall-infūzjoni	FR/H/0140/001	MA135/00101	ORPHAN EUROPE SARL	MT
Normosang 25 mg/ml, koncentrat till infusionsvätska, lösning	FR/H/0140/001	15349	ORPHAN EUROPE SARL	SE
NORMOSANG 25 mg/ml infúzny koncentrát	FR/H/0140/001	80/0348/09-S	ORPHAN EUROPE SARL	SK
Normosang 25 mg/ml, πικνό διάλυμα για παρασκευή διαλύματος προς έγχυση.	FR/H/140/01	18966	ORPHAN EUROPE SARL	CY