



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021

EMA/217572/2021

Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: human hemin

Procedure no.: PSUSA/00001629/202005

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An agency of the European Union



| Product full name (in authorisation country as per Art. 57 data) | MRP/DCP or CP Authorisation number (if not available then insert not available) | National Authorisation Number of product in the member state | 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 | 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 | RECORDATI RARE DISEASES | 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 |
| 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 |

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| Normosang 25 mg/ml koncentrat za otopinu za infuziju | not available | HR-H-963951477 | ORPHAN EUROPE SARL | HR |
| Normosang 25 mg/ml koncentrat 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 |
| Normosang, konsentrat 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 | FR/H/0140/001 | IS/1/06/015/01 | RECORDATI RARE DISEASES | IS |

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|---|---------------|------------------|-------------------------|----|
| innrennsliþykkni, lausn | | | | |
| 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 |
| 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 infúzny 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 |