



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 June 2017  
EMA/370951/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: levosimendan

Procedure no.: PSUSA/00001858/201609



| <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> |
|------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| SIMDAX 2,5 mg/ml                                                             | not available                         | 41/0221/02-S                         | ORION CORPORATION                         | SK                                              |
| Simdax 2,5 mg/ml -<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung | SE/H/0233/001                         | 1-24093                              | ORION CORPORATION                         | AT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3654787                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3654886                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3654985                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3655081                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3655180                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrado para solução<br>para perfusão                | SE/H/0233/001                         | 3655289                              | ORION CORPORATION                         | PT                                              |
| Simdax 2,5 mg/ml<br>concentrat pentru soluție<br>perfuzabilă                 | not available                         | 6449/2014/01                         | ORION CORPORATION                         | RO                                              |

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|-------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108012                            | ORION CORPORATION                         | IT                                              |
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108024                            | ORION CORPORATION                         | IT                                              |
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108036                            | ORION CORPORATION                         | IT                                              |
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108048                            | ORION CORPORATION                         | IT                                              |
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108051                            | ORION CORPORATION                         | IT                                              |
| Simdax 2,5 mg/ml di concentrato per soluzione per infusione | SE/H/0233/001                         | 035108063                            | ORION CORPORATION                         | IT                                              |
| SIMDAX 2,5 mg/ml infuusiokonsentraatti, liuosta varten      | SE/H/0233/001                         | 16326                                | ORION CORPORATION                         | FI                                              |
| Simdax 2,5 mg/ml innrennsliþykkni, lausn                    | SE/H/0233/001                         | IS/1/01/002/01                       | ORION CORPORATION                         | IS                                              |
| SIMDAX 2,5 mg/ml Koncentrát pro infuzní roztok              | not available                         | 41/282/02-C                          | ORION CORPORATION                         | CZ                                              |

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|---------------------------------------------------------------------|--------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| SIMDAX 2,5 mg/ml koncentrat till infusionsvätska, lösning           | SE/H/233/01                    | 16326                         | ORION CORPORATION                  | FI                                       |
| Simdax 2,5 mg/ml koncentrat till infusionsvätska, lösning           | SE/H/0233/001                  | 15361                         | ORION CORPORATION                  | SE                                       |
| Simdax 2,5 mg/ml koncentrat za otopinu za infuziju                  | not available                  | UP/I-530-09/11-02/209         | MEDIS ADRIA D.O.O.                 | HR                                       |
| Simdax 2,5 mg/ml koncentrárum oldatos infúzióhoz                    | not available                  | OGYI-T-8647/01                | ORION CORPORATION                  | HU                                       |
| Simdax 2,5 mg/ml koncentrárum oldatos infúzióhoz                    | not available                  | OGYI-T-8647/02                | ORION CORPORATION                  | HU                                       |
| Simdax 2,5 mg/ml konsentrat til infusjonsvæske                      | SE/H/0233/001                  | 00-9373                       | ORION CORPORATION                  | NO                                       |
| Simdax 2,5 mg/ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση | SE/H/0233/001                  | 31332/3-5-2012                | ORION CORPORATION                  | GR                                       |
| SIMDAX 2.5 mg/ml de concentrado para solución para perfusión        | SE/H/0233/001                  | 64.154                        | ORION CORPORATION                  | ES                                       |
| Симдакс 2,5 mg/ml концентрат за инфузионен разтвор                  | not available                  | 20040028                      | ORION CORPORATION                  | BG                                       |