



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 February 2025  
EMA/49179/2025  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance: anti-t lymphocyte immunoglobulin for human use, rabbit

Procedure no.: PSUSA/00010252/202406



| <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> |
|---------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Grafalon 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung     | not available                       | 2-00242                              | NEOVII BIOTECH GMBH                       | AT                                              |
| Grafalon SCT 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung | AT/H/0478/001                       | 235079                               | NEOVII BIOTECH GMBH                       | AT                                              |
| Grafalon SCT 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung | AT/H/0478/001                       | 235079                               | NEOVII BIOTECH GMBH                       | AT                                              |
| Grafalon 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung.    | not available                       | BE 137873                            | NEOVII BIOTECH GMBH                       | BE                                              |
| Grafalon 20 mg/ml<br>concentrate for solution<br>for infusion.                  | not available                       | 17186                                | NEOVII BIOTECH GMBH                       | CY                                              |
| Grafalon 20 mg/ml<br>koncentrát pro infuzní<br>roztok                           | not available                       | 59/256/97-C                          | NEOVII BIOTECH GMBH                       | CZ                                              |
| Grafalon 20 mg/ml<br>koncentrát pro infuzní<br>roztok                           | not available                       | 59/256/97-C                          | NEOVII BIOTECH GMBH                       | CZ                                              |
| Grafalon 20 mg/ml<br>koncentrát pro infuzní<br>roztok                           | not available                       | 59/256/97-C                          | NEOVII BIOTECH GMBH                       | CZ                                              |

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|-----------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Grafalon 20 mg/ml<br>koncentrát pro infuzní<br>roztok                       | not available                       | 59/256/97-C                          | NEOVII BIOTECH GMBH                       | CZ                                              |
| Grafalon 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung | not available                       | 452A/87                              | NEOVII BIOTECH GMBH                       | DE                                              |
| Grafalon 20 mg/ml<br>Konzentrat zur<br>Herstellung einer<br>Infusionslösung | not available                       | 452A/87                              | NEOVII BIOTECH GMBH                       | DE                                              |
| Grafalon, 20 mg/ml<br>infusiooni lahuse<br>kontsentraat                     | not available                       | 431004                               | NEOVII BIOTECH GMBH                       | EE                                              |
| Grafalon 20 mg/ml<br>concentrado para solución<br>para perfusión            | not available                       | 62.759                               | NEOVII BIOTECH GMBH                       | ES                                              |
| Grafalon 20 mg/ml<br>concentrado para solución<br>para perfusión            | not available                       | 62.759                               | NEOVII BIOTECH GMBH                       | ES                                              |
| GRAFALON 20 mg/ml,<br>solution à diluer pour<br>perfusion                   | not available                       | NL19125                              | NEOVII BIOTECH GMBH                       | FR                                              |
| Grafalon 20 mg/ml<br>koncentrat za otopinu za<br>infuziju.                  | not available                       | HR-H-421675779                       | NEOVII BIOTECH GMBH                       | HR                                              |

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|-----------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Grafalon 20 mg/ml koncentrátum oldatos infúzióhoz         | not available                       | OGYI-T-8999/01                       | NEOVII BIOTECH GMBH                       | HU                                              |
| Grafalon 20 mg/ml koncentrátum oldatos infúzióhoz         | not available                       | OGYI-T-8999/02                       | NEOVII BIOTECH GMBH                       | HU                                              |
| Grafalon 20 mg/ml concentrate for solution for infusion   | not available                       | PA1015/001/001                       | NEOVII BIOTECH GMBH                       | IE                                              |
| Grafalon 20 mg/ml concentrate for solution for infusion   | not available                       | PA1015/001/001                       | NEOVII BIOTECH GMBH                       | IE                                              |
| Grafalon 20 mg/ml concentrate for solution for infusion   | not available                       | PA1015/001/001                       | NEOVII BIOTECH GMBH                       | IE                                              |
| Grafalon 20 mg/ml concentrato per soluzione per infusione | AT/H/0478/001                       | 042421014                            | NEOVII BIOTECH GMBH                       | IT                                              |
| Grafalon 20 mg/ml concentrato per soluzione per infusione | AT/H/0478/001                       | 042421014                            | NEOVII BIOTECH GMBH                       | IT                                              |
| Grafalon 20 mg/ml koncentratas infuziniam tirpalui        | not available                       | LT/1/98/2648/002                     | NEOVII BIOTECH GMBH                       | LT                                              |
| Grafalon 20 mg/ml koncentratas infuziniam tirpalui.       | not available                       | LT/1/98/2648/001                     | NEOVII BIOTECH GMBH                       | LT                                              |

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| Grafalon 20 mg/ml koncentrāts infūzijai šķiduma pagatavošanai.    | not available                       | 03-0091                              | NEOVII BIOTECH GMBH                       | LV                                              |
| Grafalon 20 mg/ml concentraat voor oplossing voor infusie.        | not available                       | RVG 17602                            | NEOVII BIOTECH GMBH                       | NL                                              |
| Grafalon 20 mg/ml concentraat voor oplossing voor infusie.        | not available                       | RVG 17602                            | NEOVII BIOTECH GMBH                       | NL                                              |
| Grafalon 20 mg/ml concentraat voor oplossing voor infusie.        | not available                       | RVG 17602                            | NEOVII BIOTECH GMBH                       | NL                                              |
| Grafalon 20 mg/ml koncentrat do sporządzania roztworu do infuzji. | not available                       | 7331                                 | NEOVII BIOTECH GMBH                       | PL                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão        | not available                       | 3543485                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão        | not available                       | 3543584                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão        | not available                       | 3543782                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão        | not available                       | 3543881                              | NEOVII BIOTECH GMBH                       | PT                                              |

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|------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543485                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543584                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543782                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543881                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543485                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543584                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543782                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon, 20 mg/ml, Concentrado para solução para perfusão | not available                       | 3543881                              | NEOVII BIOTECH GMBH                       | PT                                              |
| Grafalon 20 mg/ml concentrat pentru soluție perfuzabilă    | not available                       | 7711/2015/01-02                      | NEOVII BIOTECH GMBH                       | RO                                              |

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|-------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Grafalon 20 mg/ml koncentrat till infusionsvätska, lösning. | not available                       | 14214                                | NEOVII BIOTECH GMBH                       | SE                                              |
| Grafalon 20 mg/ml koncentrat till infusionsvätska, lösning. | not available                       | 14214                                | NEOVII BIOTECH GMBH                       | SE                                              |
| Grafalon 20 mg/ml koncentrat za raztopino za infundiranje   | not available                       | H/04/00202/001                       | NEOVII BIOTECH GMBH                       | SI                                              |
| Grafalon 20 mg/ml koncentrat za raztopino za infundiranje   | not available                       | H/04/00202/001                       | NEOVII BIOTECH GMBH                       | SI                                              |
| Grafalon, 20 mg/ml infúzny koncentrát                       | not available                       | 59/0229/01-S                         | NEOVII BIOTECH GMBH                       | SK                                              |
| Grafalon, 20 mg/ml infúzny koncentrát                       | not available                       | 59/0229/01-S                         | NEOVII BIOTECH GMBH                       | SK                                              |