



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 September 2017  
EMA/604559/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: iron / parenteral preparations

Procedure no.: PSUSA/00010236/201701



| <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> |
|------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Diafer 50 mg/ml injekcinis tirpalas            | SE/H/1164/001                         | LT/1/14/3523/001                     | PHARMACOSMOS A/S                          | LT                                              |
| Diafer 50 mg/ml injekcinis tirpalas            | SE/H/1164/001                         | LT/1/14/3523/002                     | PHARMACOSMOS A/S                          | LT                                              |
| Diafer 50 mg/ml injekcinis tirpalas            | SE/H/1164/001                         | LT/1/14/3523/003                     | PHARMACOSMOS A/S                          | LT                                              |
| Diafer 50 mg/ml injekcinis tirpalas            | SE/H/1164/001                         | LT/1/14/3523/004                     | PHARMACOSMOS A/S                          | LT                                              |
| Diafer 50 mg/ml Injekční roztok                | SE/H/1164/001                         | 12/255/14-C                          | PHARMACOSMOS A/S                          | CZ                                              |
| Diafer 50 mg/ml injekčný roztok                | SE/H/1164/001                         | 12/0220/14-S                         | PHARMACOSMOS A/S                          | SK                                              |
| Diafer 50 mg/ml injektioneste, liuos           | SE/H/1164/001                         | 31802                                | PHARMACOSMOS A/S                          | FI                                              |
| Diafer 50 mg/ml Injektionslösung               | SE/H/1164/001                         | 91008.00.00                          | PHARMACOSMOS A/S                          | DE                                              |
| Diafer 50 mg/ml injektionsvätska, lösning      | SE/H/1164/001                         | 31802                                | PHARMACOSMOS A/S                          | FI                                              |
| Diafer 50 mg/ml injektionsvätska, lösning      | SE/H/1164/01/MR                       | 47595                                | PHARMACOSMOS A/S                          | SE                                              |
| Diafer 50 mg/ml oldatos injekció               | SE/H/1164/001                         | OGY-T-22649/01                       | PHARMACOSMOS A/S                          | HU                                              |
| Diafer 50 mg/ml oldatos injekció               | SE/H/1164/001                         | OGY-T-22649/02                       | PHARMACOSMOS A/S                          | HU                                              |
| Diafer 50 mg/ml oldatos injekció               | SE/H/1164/001                         | OGY-T-22649/03                       | PHARMACOSMOS A/S                          | HU                                              |
| Diafer 50 mg/ml oldatos injekció               | SE/H/1164/001                         | OGY-T-22649/04                       | PHARMACOSMOS A/S                          | HU                                              |
| Diafer 50 mg/ml oplossing voor injectie        | SE/H/1164/001                         | RVG 114220                           | PHARMACOSMOS A/S                          | NL                                              |
| Diafer 50 mg/ml otopina za injekciju           | SE/H/1164/001                         | UP/I-530-09/13-01/64                 | PHARMACOSMOS A/S                          | HR                                              |
| Diafer 50 mg/ml šķidums injekcijam             | SE/H/1164/001                         | 14-0096                              | PHARMACOSMOS A/S                          | LV                                              |
| Diafer 50 mg/ml solución inyectable            | SE/H/1164/001                         | 78616                                | PHARMACOSMOS A/S                          | ES                                              |
| Diafer 50 mg/ml solutie injectabila            | SE/H/1164/001/MR                      | 6263/2014/01                         | PHARMACOSMOS A/S                          | RO                                              |
| Diafer 50 mg/ml soluție injectabilă            | SE/H/1164/001                         | 6263/2014/02                         | PHARMACOSMOS A/S                          | RO                                              |
| Diafer 50 mg/ml soluție injectabilă            | SE/H/1164/001                         | 6263/2014/03                         | PHARMACOSMOS A/S                          | RO                                              |
| Diafer 50 mg/ml soluție injectabilă            | SE/H/1164/001                         | 6263/2014/04                         | PHARMACOSMOS A/S                          | RO                                              |
| Diafer 50 mg/ml solution for injection         | SE/H/1164/001                         | 18380/0004                           | PHARMACOSMOS A/S                          | UK                                              |
| Diafer 50 mg/ml soluzione iniettabile          | SE/H/1164/001                         | 041816012                            | PHARMACOSMOS A/S                          | IT                                              |
| Diafer 50 mg/ml soluzione iniettabile          | SE/H/1164/001                         | 041816024                            | PHARMACOSMOS A/S                          | IT                                              |
| Diafer 50 mg/ml soluzione iniettabile          | SE/H/1164/001                         | 041816036                            | PHARMACOSMOS A/S                          | IT                                              |

| <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> |
|---------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Diafer 50 mg/ml soluzione iniettabile             | SE/H/1164/001                         | 041816048                            | PHARMACOSMOS A/S                          | IT                                              |
| Diafer 50 mg/ml süstelahus                        | SE/H/1164/001                         | 840214                               | PHARMACOSMOS A/S                          | EE                                              |
| Diafer 50 mg/ml, Ενέσιμο διάλυμα                  | SE/H/1164/001                         | 305970101                            | PHARMACOSMOS A/S                          | GR                                              |
| Diafer 50 mg/ml, Ενέσιμο διάλυμα                  | SE/H/1164/001                         | 305970102                            | PHARMACOSMOS A/S                          | GR                                              |
| Diafer 50 mg/ml, Ενέσιμο διάλυμα                  | SE/H/1164/001                         | 305970103                            | PHARMACOSMOS A/S                          | GR                                              |
| Diafer 50 mg/ml, Ενέσιμο διάλυμα                  | SE/H/1164/001                         | 305970104                            | PHARMACOSMOS A/S                          | GR                                              |
| Diafer, 50 mg Fe3+/ml, roztwór do wstrzykiwań     | SE/H/1164/001                         | 21244                                | PHARMACOSMOS A/S                          | PL                                              |
| Diafer, injektionsvæske, opløsning                | SE/H/1164/001                         | 53087                                | PHARMACOSMOS A/S                          | DK                                              |
| Diafer® 50 mg/ml injeksjonsvæske, oppløsning      | SE/H/1164/001/MR                      | 13-9739                              | PHARMACOSMOS A/S                          | NO                                              |
| Diafer® 50 mg/ml Injektionslösung                 | SE/H/1164/001                         | 135493                               | PHARMACOSMOS A/S                          | AT                                              |
| Diafer® 50 mg/ml Injektionslösung                 | SE/H/1164/001                         | BE456862                             | PHARMACOSMOS A/S                          | BE                                              |
| Diafer® 50 mg/ml oplossing voor injectie          | SE/H/1164/001                         | BE456862                             | PHARMACOSMOS A/S                          | BE                                              |
| Diafer® 50 mg/ml solution for injection           | SE/H/1164/001/MR                      | PA0982/004/001                       | PHARMACOSMOS A/S                          | IE                                              |
| Diafer® 50 mg/ml solution pour injection          | SE/H/1164/001/MR                      | BE456862                             | PHARMACOSMOS A/S                          | BE                                              |
| Ferinject                                         | UK/H/0894/001                         | 39254                                | VIFOR FRANCE                              | DK                                              |
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas | UK/H/0894/001                         | LT/1/08/1133/004                     | VIFOR FRANCE                              | LT                                              |
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas | UK/H/0894/001                         | LT/1/08/1133/006                     | VIFOR FRANCE                              | LT                                              |
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas | UK/H/0894/001                         | LT/1/08/1133/002                     | VIFOR FRANCE                              | LT                                              |
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas | UK/H/0894/001                         | LT/1/08/1133/003                     | VIFOR FRANCE                              | 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> |
|-------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas                                               | UK/H/0894/001                         | LT/1/08/1133/001                     | VIFOR FRANCE                              | LT                                              |
| Ferinject 50 mg /ml injekcinis/infuzinis tirpalas                                               | UK/H/0894/001                         | LT/1/08/1133/005                     | VIFOR FRANCE                              | LT                                              |
| Ferinject 50 mg dzelzs/ml šķīdums injekcijām/infūzijām                                          | UK/H/0894/001                         | 08-0017                              | VIFOR FRANCE                              | LV                                              |
| Ferinject 50 mg Eisen/ml Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung | UK/H/0894/001                         | 1-27299                              | VIFOR FRANCE                              | AT                                              |
| Ferinject 50 mg Eisen/ml, Injektions- und Infusionslösung                                       | UK/H/0894/001                         | 66227.00.00                          | VIFOR FRANCE                              | DE                                              |
| Ferinject 50 mg Fe/ml injekcijas-/infusionsvātska, līdšning                                     | UK/H/0894/001                         | 23738                                | VIFOR FRANCE                              | SE                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/06                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/04                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/01                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/03                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/02                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg fer/ml soluție injectabilă sau perfuzabilă                                      | UK/H/0894/001/E01/MR                  | 2864/2010/05                         | VIFOR FRANCE                              | RO                                              |
| Ferinject 50 mg ferro/ml solução injetável ou para perfusão.                                    | UK/H/0894/001                         | 5047303                              | VIFOR FRANCE                              | PT                                              |
| Ferinject 50 mg ferro/ml solução injetável ou para perfusão.                                    | UK/H/0894/001                         | 5242250                              | VIFOR FRANCE                              | PT                                              |

| <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> |
|----------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Ferinject 50 mg ferro/ml solução injetável ou para perfusão.   | UK/H/0894/001                         | 5242268                              | VIFOR FRANCE                              | PT                                              |
| Ferinject 50 mg ferro/ml solução injetável ou para perfusão.   | UK/H/0894/001                         | 5047279                              | VIFOR FRANCE                              | PT                                              |
| Ferinject 50 mg ijzer/ ml, oplossing voor injectie/ infusie.   | UK/H/0894/001                         | RVG 33865                            | VIFOR FRANCE                              | NL                                              |
| Ferinject 50 mg iron/ml solution for injection/infusion        | UK/H/0894/001                         | PL 15240/0002                        | VIFOR FRANCE                              | HR                                              |
| Ferinject 50 mg iron/ml solution for injection/infusion        | UK/H/0894/001                         | PA0949/004/001                       | VIFOR FRANCE                              | IE                                              |
| Ferinject 50 mg iron/ml solution for injection/infusion        | UK/H/0894/001                         | MA869/00101                          | VIFOR FRANCE                              | MT                                              |
| Ferinject 50 mg iron/ml solution for injection/infusion        | UK/H/0894/001                         | PL 15240/0002                        | VIFOR FRANCE                              | UK                                              |
| Ferinject 50 mg iron/ml solution for injection/infusion        | UK/H/0894/001                         | PL 15240/0002                        | VIFOR FRANCE                              | UK                                              |
| Ferinject 50 mg járn/ml stungulyf/innrennsislyf, lausn         | UK/H/0894/001                         | IS/1/10/042/01                       | VIFOR FRANCE                              | IS                                              |
| Ferinject 50 mg jern/ml injeksjons-/infusjonsvæske, oppløsning | UK/H/0894/001                         | 09-7172                              | VIFOR FRANCE                              | NO                                              |
| Ferinject 50 mg rautaa/ml injektio-/infuusioneste, liuos       | UK/H/0894/001                         | 22144                                | VIFOR FRANCE                              | FI                                              |
| Ferinject 50 mg vas/ml oldatos injekció vagy infúzió           | UK/H/0894/001                         | OGYI-T-21344/04                      | VIFOR FRANCE                              | HU                                              |
| Ferinject 50 mg vas/ml oldatos injekció vagy infúzió           | UK/H/0894/001                         | OGYI-T-21344/03                      | VIFOR FRANCE                              | HU                                              |
| Ferinject 50 mg vas/ml oldatos injekció vagy infúzió           | UK/H/0894/001                         | OGYI-T-21344/01                      | VIFOR FRANCE                              | HU                                              |
| Ferinject 50 mg vas/ml oldatos                                 | UK/H/0894/001                         | OGYI-T-21344/02                      | VIFOR FRANCE                              | HU                                              |

| 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 |
|-------------------------------------------------------------------|--------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| injekció vagy infúzió                                             |                                |                               |                                    |                                          |
| Ferinject 50 mg želaza/ml roztwór do wstrzykiwań/infuzji          | UK/H/0894/001                  | 16248                         | VIFOR FRANCE                       | PL                                       |
| Ferinject 50 mg železa/ml Injekční roztok/infuzní roztok.         | UK/H/0894/001                  | 12/747/07-C                   | VIFOR FRANCE                       | CZ                                       |
| Ferinject 50 mg železa/ml, injekčný a infúzny roztok              | UK/H/0894/001                  | 12/0250/07-S                  | VIFOR FRANCE                       | SK                                       |
| Ferinject 50 mg σιδήρου ανά ml ενέσιμο διάλυμα/διάλυμα για έγχυση | UK/H/0894/001                  | 20795                         | VIFOR FRANCE                       | CY                                       |
| Ferinject 50 mg σιδήρου ανά ml ενέσιμο διάλυμα/διάλυμα για έγχυση | UK/H/0894/001                  | 59675/26-8-11                 | VIFOR FRANCE                       | GR                                       |
| Ferinject 50 mg/ml Solución inyectable y para perfusión           | UK/H/0894/001                  | 69771                         | VIFOR FRANCE                       | ES                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 386 823 6 6             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 386 924 7 1             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 219 394 8 4             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 386 933 6 2             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 219 393 1 6             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg/ml, solution injectable/pour perfusion            | UK/H/0894/001                  | 34009 386 812 4 6             | VIFOR FRANCE                       | FR                                       |
| Ferinject 50 mg ferro/ml soluzione iniettabile/per infusione      | UK/H/0894/001                  | 040251011                     | VIFOR FRANCE                       | IT                                       |
| Ferinject 50 mg ferro/ml soluzione iniettabile/per infusione      | UK/H/0894/001                  | 040251047                     | VIFOR FRANCE                       | IT                                       |

| <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> |
|---------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Ferinject 50 mg ferro/ml soluzione iniettabile/per infusione              | UK/H/0894/001                         | 040251035                            | VIFOR FRANCE                              | IT                                              |
| Ferinject 50 mg ferro/ml soluzione iniettabile/per infusione              | UK/H/0894/001                         | 040251023                            | VIFOR FRANCE                              | IT                                              |
| Ferinject, 50 mg rauda/ml süste- või infusioonilahus                      | UK/H/0894/001                         | 556607                               | VIFOR FRANCE                              | EE                                              |
| FERLIXIT 62.5                                                             | not available                         | 021455023                            | SANOFI SPA                                | IT                                              |
| FERRLECIT                                                                 | not available                         | 12/174/73/-C                         | SANOFI-AVENTIS SRO                        | CZ                                              |
| FERRLECIT                                                                 | not available                         | 12/174/73-C                          | SANOFI-AVENTIS SRO                        | CZ                                              |
| FERRLECIT 12,5 MG/ML OLDATOS INJEKCIO                                     | not available                         | OGYI-T-438/01                        | SANOFI-AVENTIS ZRT                        | HU                                              |
| Injectafer 50 mg de fer/ml solution injectable ou solution pour perfusion | UK/H/0894/001                         | BE371393                             | VIFOR FRANCE                              | BE                                              |
| Injectafer 50 mg de fer/ml solution injectable ou solution pour perfusion | UK/H/0894/001                         | BE371402                             | VIFOR FRANCE                              | BE                                              |
| Injectafer 50 mg de fer/ml solution injectable ou solution pour perfusion | UK/H/0894/001                         | 1308/10110018                        | VIFOR FRANCE                              | LU                                              |
| Injectafer 50 mg ijzer/ ml oplossing voor injectie/infusie                | UK/H/0894/001                         | BE371393                             | VIFOR FRANCE                              | BE                                              |
| Injectafer 50 mg ijzer/ ml oplossing voor injectie/infusie                | UK/H/0894/001                         | BE371402                             | VIFOR FRANCE                              | BE                                              |
| Injectafer 50 mg ijzer/ ml oplossing voor injectie/infusie                | UK/H/0894/001                         | 1308/10110018                        | VIFOR FRANCE                              | LU                                              |
| Iroprem 50 mg železa/ml raztopina za injiciranje ali infundiranje         | UK/H/0894/001/E01/MR                  | 5363-I-1295/10                       | VIFOR FRANCE                              | SI                                              |
| Iroprem 50 mg železa/ml raztopina za injiciranje ali infundiranje         | UK/H/0894/001/E01/MR                  | 5363-I-1297/10                       | VIFOR FRANCE                              | SI                                              |
| Iroprem 50 mg železa/ml raztopina za injiciranje ali infundiranje         | UK/H/0894/001/E01/MR                  | 5363-I-1296/10                       | VIFOR FRANCE                              | SI                                              |

| <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> |
|-------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Iroprem 50 mg železa/ml raztopina za injiciranje ali infundiranje | UK/H/0894/001/E01/MR                  | 5363-I-1298/10                       | VIFOR FRANCE                              | SI                                              |
| Monofer 100 mg/ml solução injectável ou para perfusão             | SE/H/0734/001                         | 5268214                              | PHARMACOSMOS A/S                          | PT                                              |
| Monofer 100 mg/ml solução injectável ou para perfusão             | SE/H/0734/001                         | 5268206                              | PHARMACOSMOS A/S                          | PT                                              |
| Monofer 100 mg/ml solução injectável ou para perfusão             | SE/H/0734/001                         | 5268172                              | PHARMACOSMOS A/S                          | PT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/001                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/002                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/003                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/004                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/005                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/006                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/007                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/008                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/009                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas                | SE/H/0734/001                         | LT/1/10/1898/010                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar                                   | SE/H/0734/001                         | LT/1/10/1898/011                     | PHARMACOSMOS A/S                          | 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> |
|---------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| infuzinis tirpalas                                      |                                       |                                      |                                           |                                                 |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas      | SE/H/0734/001                         | LT/1/10/1898/012                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas      | SE/H/0734/001                         | LT/1/10/1898/013                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas      | SE/H/0734/001                         | LT/1/10/1898/014                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas      | SE/H/0734/001                         | LT/1/10/1898/015                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injekcinis ar infuzinis tirpalas      | SE/H/0734/001                         | LT/1/10/1898/016                     | PHARMACOSMOS A/S                          | LT                                              |
| MonoFer 100 mg/ml injekcinis/infuzinis tirpalas         | SE/H/0734/001                         | LT/1/10/1898/017                     | PHARMACOSMOS A/S                          | LT                                              |
| MonoFer 100 mg/ml injekcinis/infuzinis tirpalas         | SE/H/0734/001                         | LT/1/10/1898/018                     | PHARMACOSMOS A/S                          | LT                                              |
| MonoFer 100 mg/ml injekcinis/infuzinis tirpalas         | SE/H/0734/001                         | LT/1/10/1898/019                     | PHARMACOSMOS A/S                          | LT                                              |
| Monofer 100 mg/ml injektio- /infuusioneste, liuos       | SE/H/0734/001                         | 25286                                | PHARMACOSMOS A/S                          | FI                                              |
| Monofer 100 mg/ml injektio- /infuusioneste, liuos       | SE/H/0734/001                         | 25286                                | PHARMACOSMOS A/S                          | FI                                              |
| MonoFer 100 mg/ml Injektions- oder Infusionslösung      | SE/H/0734/001                         | 1-29203                              | PHARMACOSMOS A/S                          | AT                                              |
| Monofer 100 mg/ml injektions- /infusionsvätska, lösning | SE/H/0734/001                         | 27791                                | PHARMACOSMOS A/S                          | SE                                              |
| MonoFer 100 mg/ml Lösung zur Injektion und Infusion     | SE/H/0734/001                         | 75060.00.00                          | PHARMACOSMOS A/S                          | DE                                              |
| MonoFer 100 mg/ml Lösung zur Injektion und Infusion     | SE/H/0734/001                         | 2012030052                           | PHARMACOSMOS A/S                          | 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> |
|----------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| MonoFer 100 mg/ml oplossing voor injectie/infusie  | SE/H/0734/001                         | 2012030052                           | PHARMACOSMOS A/S                          | LU                                              |
| Monofer 100 mg/ml oplossing voor injectie/infusie  | SE/H/0734/001                         | RVG 103070                           | PHARMACOSMOS A/S                          | NL                                              |
| MONOFER 100 mg/ml šķīdums injekcijām vai infūzijām | SE/H/0734/001                         | 10-0203                              | PHARMACOSMOS A/S                          | LV                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila  | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |

| <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> |
|----------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| injectabila/perfuzabila                                        |                                       |                                      |                                           |                                                 |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01-19                      | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solutie injectabila/perfuzabila              | SE/H/0734/001                         | 8145/2015/01                         | PHARMACOSMOS A/S                          | RO                                              |
| Monofer 100 mg/ml solution for injection/infusion              | SE/H/0734/001                         | PL 18380/001                         | PHARMACOSMOS A/S                          | UK                                              |
| MonoFer 100 mg/ml solution pour injection/perfusion            | SE/H/0734/001                         | 2012030052                           | PHARMACOSMOS A/S                          | LU                                              |
| Monofer 100 mg/ml διάλυμα για ένεση ή έγχυση                   | SE/H/0734/001                         | 77811/28-12-2015                     | PHARMACOSMOS A/S                          | GR                                              |
| Monofer, 100 mg/ml süste- vői infusioonilahus                  | SE/H/0734/001                         | 671910                               | PHARMACOSMOS A/S                          | EE                                              |
| Monofer, injektions- og infusionsvæske, opløsning              | SE/H/0734/001                         | 43747                                | PHARMACOSMOS A/S                          | DK                                              |
| MonoFer® 100 mg/ml injeksjonsvæske/ infusionsvæske, oppløsning | SE/H/0734/001/DC                      | 08-6145                              | PHARMACOSMOS A/S                          | NO                                              |
| MonoFer® 100 mg/ml                                             | SE/H/0734/001                         | IS/1/09/010/01                       | PHARMACOSMOS A/S                          | IS                                              |

| <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> |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| stungulyf/innrennsliislyf, lausn                                                                                     |                                       |                                      |                                           |                                                 |
| Monoferro 100 mg/ml solución inyectable y para perfusión                                                             | SE/H/0734/001                         | 72381                                | PHARMACOSMOS A/S                          | ES                                              |
| Monover 100 mg/ml roztwór do wstrzykiwan i infuzji                                                                   | SE/H/0734/001                         | 16535                                | PHARMACOSMOS A/S                          | PL                                              |
| Monover 100mg/ml solution for injection/infusion (ampoules)                                                          | SE/H/0734/001                         | PA0982/002/001                       | PHARMACOSMOS A/S                          | IE                                              |
| Monover 100mg/ml solution for injection/infusion (vials)                                                             | SE/H/0734/001                         | PA0982/002/002                       | PHARMACOSMOS A/S                          | IE                                              |
| Venofer                                                                                                              | not available                         | 12/0852/92-S                         | VIFOR FRANCE                              | SK                                              |
| Venofer 100 mg fer/5 ml soluție injectabilă/perfuzabilă                                                              | not available                         | 4035/2003/01                         | VIFOR FRANCE                              | RO                                              |
| Venofer 100 mg fer/5 ml soluție injectabilă/perfuzabilă                                                              | not available                         | 4035/2003/02                         | VIFOR FRANCE                              | RO                                              |
| Venofer 100 mg/5ml Solução injectável                                                                                | not available                         | 5450176                              | VIFOR FRANCE                              | PT                                              |
| Venofer 100 mg/5ml Solução injectável                                                                                | not available                         | 8109603                              | VIFOR FRANCE                              | PT                                              |
| Venofer 20 mg de fer / ml, solution injectable ou solution à diluer pour perfusion                                   | UK/H/0313/001                         | BE 345502                            | VIFOR FRANCE                              | BE                                              |
| Venofer 20 mg de fer / ml, solution injectable ou solution à diluer pour perfusion                                   | UK/H/0313/001                         | 1308/01/07/0069                      | VIFOR FRANCE                              | LU                                              |
| Venofer 20 mg Eisen / ml – Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung - Eisen-Saccharose | UK/H/0313/001                         | 1-23754                              | VIFOR FRANCE                              | AT                                              |
| Venofer 20 mg Fe / ml                                                                                                | not available                         | 6462062.00.00                        | VIFOR FRANCE                              | 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> |
|-------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Injektionslösung                                                                                |                                       |                                      |                                           |                                                 |
| Venofer 20 mg ijzer / ml, oplossing voor injectie of concentraat voor oplossing voor infusie    | UK/H/0313/001                         | BE 216492                            | VIFOR FRANCE                              | BE                                              |
| Venofer 20 mg ijzer / ml, oplossing voor injectie of concentraat voor oplossing voor infusie    | UK/H/0313/001                         | BE 216492                            | VIFOR FRANCE                              | BE                                              |
| Venofer 20 mg ijzer / ml, oplossing voor injectie of concentraat voor oplossing voor infusie    | UK/H/0313/001                         | BE 345502                            | VIFOR FRANCE                              | BE                                              |
| Venofer 20 mg ijzer per ml, oplossing voor injectie / concentraat voor oplossing voor infusie   | not available                         | RVG 20690                            | VIFOR FRANCE                              | NL                                              |
| Venofer 20 mg ijzer per ml, oplossing voor injectie of concentraat voor oplossing voor infusie  | UK/H/0313/001                         | 1308/01/07/0069                      | VIFOR FRANCE                              | LU                                              |
| Venofer 20 mg iron / ml, solution for injection or concentrate for solution for infusion        | UK/H/0313/001                         | PL 15240/0001                        | VIFOR FRANCE                              | UK                                              |
| Venofer 20 mg iron/ml, solution for injection or concentrate for solution for infusion, ampoule | UK/H/0313/001                         | PA 949/1/1                           | VIFOR FRANCE                              | IE                                              |
| Venofer 20 mg iron/ml, solution for injection or concentrate for solution for infusion, vial    | UK/H/0313/001                         | PA 949/1/2                           | VIFOR FRANCE                              | IE                                              |
| Venofer 20 mg järn/ml, injektionsvätska, lösning eller koncentrat till infusionsvätska, lösning | UK/H/0313/001                         | 15754                                | VIFOR FRANCE                              | SE                                              |
| Venofer 20 mg jern per ml                                                                       | not available                         | 99-4553                              | VIFOR FRANCE                              | NO                                              |

| <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> |
|-------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| injeksjonsvæske, oppløsning eller konsentrat til infusjonsvæske                                 |                                       |                                      |                                           |                                                 |
| Venofer 20 mg rautaa /ml injektioneste, liuos tai infuusiokonsentraatti, liuosta varten.        | UK/H/0313/001                         | 14727                                | VIFOR FRANCE                              | FI                                              |
| Venofer 20 mg σιδήρου / ml ενέσιμο διάλυμα ή πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση | UK/H/0313/001                         | 50875/10/8-11-11                     | VIFOR FRANCE                              | GR                                              |
| Venofer 20 mg, di ferro per ml soluzione iniettabile o concentrato per soluzione per infusione. | UK/H/0313/001                         | 035283011                            | VIFOR FRANCE                              | IT                                              |
| Venofer 20 mg/ml injekcinis tirpalas                                                            | not available                         | LT/1/04/0097/001                     | VIFOR FRANCE                              | LT                                              |
| Venofer 20 mg/ml oldatos injekció vagy koncentrátum oldatos infúzióhoz                          | not available                         | OGYI-T-6362/01                       | VIFOR FRANCE                              | HU                                              |
| Venofer 20 mg/ml šķidums injekcijām                                                             | not available                         | 98-0243                              | VIFOR FRANCE                              | LV                                              |
| Venofer 20 mg/ml Solución inyectable o concentrado para solución para perfusion                 | UK/H/0313/001                         | 64.000                               | VIFOR FRANCE                              | ES                                              |
| VENOFER 20 mg/ml solution injectable (IV)                                                       | not available                         | 34009 561 896 3 2                    | VIFOR FRANCE                              | FR                                              |
| VENOFER 20 mg/ml solution injectable (IV)                                                       | not available                         | 34009 579 152 6 1                    | VIFOR FRANCE                              | FR                                              |
| VENOFER 20 mg/ml solution injectable (IV)                                                       | not available                         | 34009 571 283 4 0                    | VIFOR FRANCE                              | FR                                              |
| Venofer 20 mg/ml süstelähus/infusioonilahuse kontsentraat                                       | not available                         | 454104                               | VIFOR FRANCE                              | EE                                              |
| Venofer Injekční roztok                                                                         | not available                         | 12/051/04-C                          | VIFOR FRANCE                              | CZ                                              |
| VENOFER, 20 mg jonów żelaza                                                                     | not available                         | R/1920                               | VIFOR FRANCE                              | PL                                              |

| <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> |
|--------------------------------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| (III)/ml, roztwór do wstrzykiwań i infuzji                                                                         |                                       |                                      |                                           |                                                 |
| Venofer, injektionsvæske, opløsning og koncentrat til infusionsvæske, opløsning                                    | UK/H/0313/001                         | 31111                                | VIFOR FRANCE                              | DK                                              |
| Venofer® 20 mg járn/ml stungulyf, lausn og innrennslispykkni, lausn.                                               | not available                         | IS/1/01/063/01                       | VIFOR FRANCE                              | IS                                              |
| ФЕРИНЖЕКТ 50 мг железа/ml инъекционен/инфузионен разтвор. Ferinject 50mg iron/ml solution for injection / infusion | UK/H/0894/001/E01/MR                  | 20100482                             | VIFOR FRANCE                              | BG                                              |