



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2018
EMA/34222/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nadroparin

Procedure no.: PSUSA/00002104/201803



| 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 |
|---------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Fraxiparina 5700 U.I. anti-Xa/0,6 ml solução injectável | not available | 2154086 | ASPEN PHARMA TRADING LIMITED | PT |
| FRAXODI® 19.000 I.E. anti-Xa/ml Injektionslösung | DE/H/0808/007 | 49834.00.00 | ASPEN PHARMA TRADING LIMITED | DE |
| FRAXIPARINE 3.800 IE (Anti-Xa)/0,4 ml oplossing voor injectie | not available | BE158776 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 5.700 IE (Anti-Xa)/0,6 ml oplossing voor injectie | not available | BE138704 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 7 600 U.I. Axa/0,8 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 332 465 4 9 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 9.500 UI (Anti-Xa)/1,0 ml solution injectable | not available | 206/03/10/7887 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine 9.500 IE (Anti-Xa)/1,0 ml Injektionslösung | not available | BE138722 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxodi 11400 U.I. anti-Xa/0,6 ml solução injectável | not available | 3500980 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparine 7.600 IE (Anti-Xa)/0,8 ml Injektionslösung | not available | 2003107886 | ASPEN PHARMA TRADING LIMITED | LU |

| 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 |
|---------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE 2.850 IE (Anti-Xa)/0,3 ml oplossing voor injectie | not available | BE138713 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxodi 15200 U.I. anti-Xa/0,8 ml solução injectável | not available | 3501285 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxodi 11400 U.I. anti-Xa/0,6 ml solução injectável | not available | 3501186 | ASPEN PHARMA TRADING LIMITED | PT |
| FRAXODI 19.000 UI (anti-Xa)/1 ml - solution injectable | not available | BE217716 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINA 9.500 U.I. antiXa/1 ml soluzione iniettabile | not available | 026736102 | ASPEN PHARMA TRADING LIMITED | IT |
| Fraxiparina 2850 U.I. anti-Xa/0,3 ml solução injectável | not available | 8748004 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 0,6 ml solución inyectable | not available | 58982 | ASPEN PHARMA TRADING LIMITED | ES |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |

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| FRAXIPARINE® 7600 i.e. anti-Xa/0,8 ml raztopina za injiciranje | not available | H/99/00658/004 | ASPEN PHARMA TRADING LIMITED | SI |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE® 9500 i.e. anti-Xa/1,0 ml raztopina za injiciranje | not available | H/99/00658/005 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINE® 2850 i.e. anti-Xa/0,3 ml raztopina za injiciranje | not available | H/99/00658/001 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINE 7.600 UI (Anti-Xa)/0,8 ml solution injectable | not available | 206/03/10/7886 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparina 0,3 ml solución inyectable | not available | 58496 | ASPEN PHARMA TRADING LIMITED | ES |
| Fraxiparine 9.500 IE (Anti-Xa)/1,0 ml Injektionslösung | not available | 2003107887 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine 5.700 IE/ 0,6 ml oplossing voor injectie | not available | RVG 11877 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparine 3.800 IE/ 0,4 ml oplossing voor injectie | not available | RVG 15963 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparina 7600 U.I. anti-Xa/0,8 ml solução injectável | not available | 8775510 | ASPEN PHARMA TRADING LIMITED | PT |

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| Fraxiparina 7600 U.I. anti-Xa/0,8 ml solução injectável | not available | 8775528 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina Forte 1 ml solución inyectable | not available | 63498 | ASPEN PHARMA TRADING LIMITED | ES |
| FRAXODI 15 200 U.I. AXa/0,8 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 347 331-9 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 19 000 U.I. Axa/1 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 334 8 2 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 2.850 UI (Anti-Xa)/0,3 ml solution injectable | not available | BE138713 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine® 0,8 7.600 I.E. anti-Xa / 0,8 ml Injektionslösung | DE/H/0808/005 | 40533.04.00 | ASPEN PHARMA TRADING LIMITED | DE |
| FRAXODI 15.200 IE (anti-Xa)/0,8 ml - oplossing voor injectie | not available | BE217707 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 7.600 IE (Anti-Xa)/0,8 ml oplossing voor injectie | not available | BE158785 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine® 0,2 1.900 I.E. anti-Xa / 0,2 ml Injektionslösung | DE/H/0808/001 | 40533.00.00 | ASPEN PHARMA TRADING LIMITED | DE |

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| FRAXODI 19.000 IE (Anti-Xa)/1 ml - Injektionslösung | not available | BE217716 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine Forte 19.000 IE/ 1 ml oplossing voor injectie | not available | RVG 23796 | ASPEN PHARMA TRADING LIMITED | NL |
| FRAXIPARINE 2 850 U.I. Axa/0,3 ml, solution injectable (S.C) en seringue pré-remplie | not available | 34009 327 827 9 6 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 15.200 IE (ANTI-XA)/0,8 ML - OPLOSSING VOOR INJECTIE | not available | 0206/07019188 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 11.400 UI antiXa/0,6 ml soluzione iniettabile | not available | 036458014 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXIPARINE® 5700 i.e. anti-Xa/0,6 ml raztopina za injiciranje | not available | H/99/00658/003 | ASPEN PHARMA TRADING LIMITED | SI |
| Fraxiparin - Fertigspritzen | not available | 1-21067 | ASPEN PHARMA TRADING LIMITED | AT |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |

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| FRAXIPARINE 5.700 UI (Anti-Xa)/0,6 ml solution injectable | not available | 206/03/10/7885 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE 3.800 UI (Anti-Xa)/0,4 ml solution injectable | not available | 206/03/10/7884 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXIPARINE 2.850 UI (Anti-Xa)/0,3 ml solution injectable | not available | 206/03/10/7883 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 19.000 UI (anti-Xa)/1 ml - solution injectable | not available | 2007019188 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE MULTI | not available | 16/0281/90-C/S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE MULTI | not available | 16/0281/90-C/S | ASPEN PHARMA TRADING LIMITED | SK |
| FRAXIPARINE 47.500 UI (Anti-Xa)/5,0 ml solution injectable | not available | 2011110020 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine Forte | not available | 16/0184/99-S | ASPEN PHARMA TRADING LIMITED | SK |

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| Fraxiparine 2.850 IE (Anti-Xa)/0,3 ml Injektionslösung | not available | 2003107883 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 15.200 UI (anti-Xa)/0,8 ml - solution injectable | not available | 2013080254 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 19.000 IE (anti-Xa)/1 ml - oplossing voor injectie | not available | 0206/07019188 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine 3.800 IE (Anti-Xa)/0,4 ml Injektionslösung | not available | 2003107884 | ASPEN PHARMA TRADING LIMITED | LU |
| Fraxiparine 5.700 IE (Anti-Xa)/0,6 ml Injektionslösung | not available | 2003107885 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 11.400 UI (anti-Xa)/0,6 ml - solution injectable | not available | 0206/07019188 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 15.200 UI (anti-Xa)/0,8 ml - solution injectable | not available | BE217707 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine 47.500 IE (Anti-Xa)/5,0 ml Injektionslösung | not available | 2011110020 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXODI 11.400 IE (Anti-Xa)/0,6 ml - Injektionslösung | not available | 0206/07019188 | ASPEN PHARMA TRADING LIMITED | LU |

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| FRAXODI 11.400 UI (anti-Xa)/0,6 ml - solution injectable | not available | BE217691 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 9.500 IE (Anti-Xa)/1,0 ml oplossing voor injectie | not available | BE138722 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 7.600 UI (Anti-Xa)/0,8 ml solution injectable | not available | BE158785 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 9.500 UI (Anti-Xa)/1,0 ml solution injectable | not available | BE138722 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXODI 11.400 IE (anti-Xa)/0,6 ml - oplossing voor injectie | not available | BE217691 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 3.800 UI (Anti-Xa)/0,4 ml solution injectable | not available | BE158776 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 47.500 IE (Anti-Xa)/5,0 ml oplossing voor injectie | not available | BE388394 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXODI 19.000 IE (anti-Xa)/1 ml - oplossing voor injectie | not available | BE217716 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 2850 IU AXa/0,3 ml ενέσιμο διάλυμα | not available | 19116 | ASPEN PHARMA TRADING LIMITED | CY |

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| FRAXIPARINE 5700 IU AXa/0,6 ml ενέσιμο διάλυμα | not available | 19117 | ASPEN PHARMA TRADING LIMITED | CY |
| FRAXIPARINE 5.700 UI (Anti-Xa)/0,6 ml solution injectable | not available | BE138704 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 47.500 UI (Anti-Xa)/5,0 ml solution injectable | not available | BE388394 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine® 1,0 9.500 I.E. anti-Xa / 1,0 ml Injektionslösung | DE/H/0808/006 | 40533.05.00 | ASPEN PHARMA TRADING LIMITED | DE |
| FRAXODI 15.200 IE (Anti-Xa)/0,8 ml - Injektionslösung | not available | BE217707 | ASPEN PHARMA TRADING LIMITED | BE |
| Fraxiparine® 0,6 5.700 I.E. anti-Xa / 0,6 ml Injektionslösung | DE/H/0808/004 | 40533.03.00 | ASPEN PHARMA TRADING LIMITED | DE |
| Fraxiparine® 0,4 3.800 I.E. anti-Xa / 0,4 ml Injektionslösung | DE/H/0808/003 | 40533.02.00 | ASPEN PHARMA TRADING LIMITED | DE |
| Fraxiparine® 0,3 2.850 I.E. anti-Xa / 0,3 ml Injektionslösung | DE/H/0808/002 | 40533.01.00 | ASPEN PHARMA TRADING LIMITED | DE |
| FRAXODI 11.400 IE (Anti-Xa)/0,6 ml - Injektionslösung | not available | BE217691 | ASPEN PHARMA TRADING LIMITED | BE |

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| Fraxiparine 7.600 IE (Anti-Xa)/0,8 ml Injektionslösung | not available | BE158785 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 5 700 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 327 828 5 7 | ASPEN PHARMA TRADING LIMITED | FR |
| Fraxiparine 3.800 IE (Anti-Xa)/0,4 ml Injektionslösung | not available | BE158776 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 9 500 U.I. Axa/1 ml, solution injectable en flacon | not available | 34009 562 056-9 | ASPEN PHARMA TRADING LIMITED | FR |
| Fraxiparine 5.700 IE (Anti-Xa)/0,6 ml Injektionslösung | not available | BE138704 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXODI 11 400 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 328 8 1 | ASPEN PHARMA TRADING LIMITED | FR |
| Fraxiparine 2.850 IE (Anti-Xa)/0,3 ml Injektionslösung | not available | BE138713 | ASPEN PHARMA TRADING LIMITED | BE |
| FRAXIPARINE 3 800 U.I. Axa/0,4 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 332 463 1 0 | ASPEN PHARMA TRADING LIMITED | FR |

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| FRAXIPARINE 9 500 U.I. Axa/1 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 327 834 5 8 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 1 900 U.I. Axa/0,2 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 332 462 5 9 | ASPEN PHARMA TRADING LIMITED | FR |
| Fraxiparina Forte 0,6 ml solución inyectable | not available | 63497 | ASPEN PHARMA TRADING LIMITED | ES |
| Fraxiparina 0,8 ml solución inyectable | not available | 61783 | ASPEN PHARMA TRADING LIMITED | ES |
| Fraxiparina 0,4 ml solución inyectable | not available | 58983 | ASPEN PHARMA TRADING LIMITED | ES |
| Fraxiparine Forte 15.200 IE/ 0,8 ml oplossing voor injectie | not available | RVG 23795 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparine 7.600 IE/ 0,8ml oplossing voor injectie | not available | RVG 15965 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparine 2.850 IE/ 0,3 ml oplossing voor injectie | not available | RVG 11876 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparine 9.500 IE/ 1 ml oplossing voor injectie | not available | RVG 11878 | ASPEN PHARMA TRADING LIMITED | NL |

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| Fraxiparine Forte 11.400 IE/ 0,6 ml oplossing voor injectie | not available | RVG 23794 | ASPEN PHARMA TRADING LIMITED | NL |
| Fraxiparina Forte 0,8 ml solución inyectable | not available | 63496 | ASPEN PHARMA TRADING LIMITED | ES |
| FRAXIPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniettabile | not available | 026736088 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXIPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniettabile | not available | 026736090 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXODI 19.000 UI antiXa/1 ml soluzione iniettabile | not available | 036458077 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXODI 15.200 UI antiXa/0,8 ml soluzione iniettabile | not available | 036458040 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXIPARINA 2.850 U.I. antiXa/0,3 ml soluzione iniettabile | not available | 026736064 | ASPEN PHARMA TRADING LIMITED | IT |
| FRAXIPARINE 9500 i.e. anti-Xa/ml raztopina za injiciranje v večodmerni viali | not available | H/99/00658/006 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINE® FORTE 19000 i.e. anti-Xa/1,0 ml raztopina za injiciranje | not available | H/03/00658/009 | ASPEN PHARMA TRADING LIMITED | SI |

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| FRAXIPARINE® FORTE 15200 i.e. anti-Xa/0,8 ml raztopina za injiciranje | not available | H/03/00658/008 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINE® FORTE 11400 i.e. anti-Xa/0,6 ml raztopina za injiciranje | not available | H/03/00658/007 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINE® 3800 i.e. anti-Xa/0,4 ml raztopina za injiciranje | not available | H/99/00658/002 | ASPEN PHARMA TRADING LIMITED | SI |
| FRAXIPARINA 3.800 U.I. antiXa/0,4 ml soluzione iniettabile | not available | 026736076 | ASPEN PHARMA TRADING LIMITED | IT |
| Fraxiparina 3800 U.I. anti-Xa/0,4 ml solução injectável | not available | 8748053 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxodi 15200 U.I. anti- Xa/0,8 ml solução injectável | not available | 3501384 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxodi 15200 U.I. anti- Xa/0,8 ml solução injectável | not available | 3501483 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 2850 U.I. anti-Xa/0,3 ml solução injectável | not available | 8748046 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 2850 U.I. anti-Xa/0,3 ml solução injectável | not available | 8748012 | ASPEN PHARMA TRADING LIMITED | PT |

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| Fraxodi 11400 U.I. anti-Xa/0,6 ml solução injectável | not available | 3501087 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 5700 U.I. anti-Xa/0,6 ml solução injectável | not available | 8748095 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 5700 U.I. anti-Xa/0,6 ml solução injectável | not available | 8775502 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparina 3800 U.I. anti-Xa/0,4 ml solução injectável | not available | 8748061 | ASPEN PHARMA TRADING LIMITED | PT |
| FRAXIPARINE® | not available | 16826/01-08-2017 | ASPEN PHARMA TRADING LIMITED | GR |
| FRAXIPARINE 7600 UI anti-factor Xa/0,8 ml soluție injectabilă | not available | 2521/2010/01 | ASPEN PHARMA TRADING LIMITED | RO |
| FRAXIPARINE 5700 UI anti-factor Xa/0,6 ml soluție injectabilă | not available | 2520/2010/01 | ASPEN PHARMA TRADING LIMITED | RO |
| FRAXIPARINE 2850 UI anti-factor Xa/0,3 ml soluție injectabilă | not available | 2518/2010/01 | ASPEN PHARMA TRADING LIMITED | RO |
| FRAXIPARINE 3800 UI anti-factor Xa/0,4 ml soluție injectabilă | not available | 2519/2010/01 | ASPEN PHARMA TRADING LIMITED | RO |

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| FRAXIPARINE® | not available | 16826/01-08-2017 | ASPEN PHARMA TRADING LIMITED | GR |
| FRAXIPARINE® | not available | 16826/01-08-2017 | ASPEN PHARMA TRADING LIMITED | GR |
| Fraxiparine® multi 9.500 I.E. / 1,0 ml Injektionslösung | not available | 35828.00.00 | ASPEN PHARMA TRADING LIMITED | DE |
| Fraxodi 11 400 NE/0,6 ml oldatos injekció | not available | OGYI-T-8015/02 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxodi 15 200 NE/0,8 ml oldatos injekció | not available | OGYI-T-8015/03 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxodi 19 000 NE/1,0 ml oldatos injekció | not available | OGYI-T-8015/04 | ASPEN PHARMA TRADING LIMITED | HU |
| FRAXIPARINE, 2850 RÜ anti-Xa/0,3 ml süstelahus süstlis | not available | 419103 | ASPEN PHARMA TRADING LIMITED | EE |
| FRAXIPARINE, 7600 RÜ anti-Xa/0,8 ml süstelahus süstlis | not available | 212998 | ASPEN PHARMA TRADING LIMITED | EE |
| FRAXIPARINE, 5700 RÜ anti-Xa/0,6 ml süstelahus süstlis | not available | 212898 | ASPEN PHARMA TRADING LIMITED | EE |
| FRAXIPARINE, 3800 RÜ anti-Xa/0,4 ml süstelahus süstlis | not available | 212698 | ASPEN PHARMA TRADING LIMITED | EE |

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| Fraxiparine 3800 IU anti-Xa/0,4 ml otopina za injekciju | not available | UP/I-530-09/12-02/408 | ASPEN PHARMA TRADING LIMITED | HR |
| Fraxiparine 5700 IU anti-Xa/0,6 ml otopina za injekciju | not available | UP/I-530-09/12-02/409 | ASPEN PHARMA TRADING LIMITED | HR |
| Fraxiparine 7600 IU anti-Xa/0,8 ml otopina za injekciju | not available | UP/I-530-09/12-02/410 | ASPEN PHARMA TRADING LIMITED | HR |
| Fraxiparine 2850 IU anti-Xa/0,3 ml otopina za injekciju | not available | UP/I-530-09/12-02/407 | ASPEN PHARMA TRADING LIMITED | HR |
| Fraxiparine 2850 NE/0,3 ml oldatos injekció | not available | OGYI-T-6770/02 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 2850 NE/0,3 ml oldatos injekció | not available | OGYI-T-6770/09 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 3800 NE/0,4 ml oldatos injekció | not available | OGYI-T-6770/08 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 3800 NE/0,4 ml oldatos injekció | not available | OGYI-T-6770/03 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 3800 NE/0,4 ml oldatos injekció | not available | OGYI-T-6770/10 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 5700 NE/0,6 ml oldatos injekció | not available | OGYI-T-6770/04 | ASPEN PHARMA TRADING LIMITED | 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 |
|-----------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Fraxiparine 5700 NE/0,6 ml oldatos injekció | not available | OGYI-T-6770/11 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 9500 NE/1,0 ml oldatos injekció | not available | OGYI-T-6770/06 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine Multi 47 500 NE/5 ml többadagos oldatos injekció | not available | OGYI-T-6770/07 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 7600 NE/0,8 ml oldatos injekció | not available | OGYI-T-6770/05 | ASPEN PHARMA TRADING LIMITED | HU |
| Fraxiparine 2 850 j.m. AXa/0,3 ml, roztwór do wstrzykiwań | not available | R/0756 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine 3 800 j.m. AXa/0,4 ml, roztwór do wstrzykiwań | not available | R/7168 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine 5 700 j.m. AXa/0,6 ml, roztwór do wstrzykiwań | not available | R/0757 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine 7 600 j.m. AXa/0,8 ml, roztwór do wstrzykiwań | not available | R/7169 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine 9 500 j.m. AXa/1 ml, roztwór do wstrzykiwań | not available | R/0758 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine Multi (Nadroparinum calcicum) 9 500 j.m. AXa/ml (47 | not available | 4873 | ASPEN PHARMA TRADING LIMITED | PL |

| 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 |
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| 500 j.m. AXa/5 ml), roztwór do wstrzykiwań | | | | |
| Fraxiparine Multi (Nadroparinum calcicum) 9 500 j.m. AXa/ml (142 500 j.m. AXa/15 ml),roztwór do wstrzykiwań | not available | 4874 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxodi (Nadroparinum calcicum) 15 200 j.m. AXa/0,8 ml, roztwór do wstrzykiwań | not available | 8370 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxodi (Nadroparinum calcicum) 11400 j.m. AXa/0,6 ml, roztwór do wstrzykiwań | not available | 8369 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxodi (Nadroparinum calcicum)19 000 j.m. AXa/1 ml, roztwór do wstrzykiwań | not available | 8371 | ASPEN PHARMA TRADING LIMITED | PL |
| Fraxiparine 47500 anti- Xa TV/5 ml injekcinis tirpalas | not available | LT/1/98/0027/007 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine 2850 anti-Xa TV/0,3 ml injekcinis tirpalas | not available | LT/1/98/0027/004 | ASPEN PHARMA TRADING LIMITED | LT |

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|----------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Fraxiparine 2850 anti-Xa TV/0,3 ml injekcinis tirpalas | not available | LT/1/98/0027/003 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine 3800 anti-Xa TV/0,4 ml injekcinis tirpalas | not available | LT/1/98/0027/005 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine 5700 anti-Xa TV/0,6 ml injekcinis tirpalas | not available | LT/1/98/0027/001 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine 3800 anti-Xa TV/0,4 ml injekcinis tirpalas | not available | LT/1/98/0027/006 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine 7600 anti-Xa TV/0,8 ml injekcinis tirpalas | not available | LT/1/98/0027/002 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine Forte 11 400 anti-Xa TV/0,6 ml injekcinis tirpalas | not available | LT/1/2000/1383/002 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine Forte 11 400 anti-Xa TV/0,6 ml injekcinis tirpalas | not available | LT/1/2000/1383/001 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine Forte 15 200 anti-Xa TV/0,8 ml injekcinis tirpalas | not available | LT/1/2000/1383/003 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine Forte 19 000 anti-Xa TV/1,0 ml injekcinis tirpalas | not available | LT/1/2000/1383/006 | ASPEN PHARMA TRADING LIMITED | LT |

| 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 |
|-----------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Fraxiparine Forte 19 000 anti-Xa TV/1,0 ml injekcinis tirpalas | not available | LT/1/2000/1383/005 | ASPEN PHARMA TRADING LIMITED | LT |
| Fraxiparine multidoze 47 500 SV AXa / 5 ml šķīdums injekcijām | not available | 10-0383 | ASPEN PHARMA TRADING LIMITED | LV |
| Fraxiparine 3800 SV AXa/ 0,4 ml, šķīdums injekcijām pilnšļircē | not available | 98-0534 | ASPEN PHARMA TRADING LIMITED | LV |
| Fraxiparine 2850 SV AXa/ 0,3 ml, šķīdums injekcijām pilnšļircē | not available | 98-0654 | ASPEN PHARMA TRADING LIMITED | LV |
| Fraxiparine 5700 SV AXa/ 0,6 ml, šķīdums injekcijām pilnšļircē | not available | 98-0535 | ASPEN PHARMA TRADING LIMITED | LV |
| Fraxiparine 7600 SV AXa / 0,8 ml, šķīdums injekcijām pilnšļircē | not available | 98-0655 | ASPEN PHARMA TRADING LIMITED | LV |
| Fraxiparine Forte 15 200 anti-Xa TV/0,8 ml injekcinis tirpalas | not available | LT/1/2000/1383/004 | ASPEN PHARMA TRADING LIMITED | LT |
| FRAXIPARINE Injekční roztok v předplněné injekční stříkačce | not available | 16/281/90-C | ASPEN PHARMA TRADING LIMITED | CZ |
| FRAXIPARIN MULTI Injekční roztok | not available | 16/734/99-C | ASPEN PHARMA TRADING LIMITED | CZ |

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|------------------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| FRAXIPARINE FORTE Injekční roztok v předplněné injekční stříkačce | not available | 16/043/00-C | ASPEN PHARMA TRADING LIMITED | CZ |
| FRAXIPARINE 9500 UI anti-factor Xa/1 ml multidozáž soluție injectabilă | not available | 10303/2017/01 | ASPEN PHARMA TRADING LIMITED | RO |
| Fraxiparine 47.500 IE (Anti-Xa)/5,0 ml Injektionslösung | not available | BE388394 | ASPEN PHARMA TRADING LIMITED | BE |
| ФРАКСИПАРИН 9 500 anti-Xa IU/ml инжекционен разтвор | not available | 20000338 | ASPEN PHARMA TRADING LIMITED | BG |
| Fraxiparine® 0,3 duo 2.850 I.E. / 0,3 ml Injektionslösung | not available | 40539.01.00 | ASPEN PHARMA TRADING LIMITED | DE |
| FRAXIPARINE 9 500 U.I. Axa/1 ml, solution injectable en flacon | not available | 34009 562 057-5 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 3 800 U.I. Axa/0,4 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 300 735 1 3 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 11.400 IE (Anti-Xa)/0,6 ml - Injektionslösung | not available | 2013080255 | ASPEN PHARMA TRADING LIMITED | LU |

| 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 |
|------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| FRAXIPARINE 5 700 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 334 876 1 4 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 5 700 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 327 831 6 8 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 19 000 U.I. Axa/1 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 336 0 4 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 19 000 U.I. Axa/1 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 335 4 3 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 11 400 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 330 2 4 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 11 400 U.I. Axa/0,6 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 347 329 4 2 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 1 900 U.I. Axa/0,2 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 556 794 1 7 | ASPEN PHARMA TRADING LIMITED | FR |

| 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 |
|------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| FRAXIPARINE 2 850 U.I. Axa/0,3 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 333 891 7 8 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 2 850 U.I. Axa/0,3 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 327 825 6 7 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 7 600 U.I. Axa/0,8 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 334 889 6 3 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXIPARINE 9 500 U.I. Axa/1 ml, solution injectable (S.C.) en seringue pré-remplie | not available | 34009 327 832 2 9 | ASPEN PHARMA TRADING LIMITED | FR |
| FRAXODI 19.000 IE (Anti-Xa)/1 ml - Injektionslösung | not available | 2007019188 | ASPEN PHARMA TRADING LIMITED | LU |
| FRAXIPARINE 9500 UI anti-factor Xa/1 ml multidoză soluție injectabilă | not available | 10303/2017/02 | ASPEN PHARMA TRADING LIMITED | RO |
| FRAXIPARINE 9500 UI anti-factor Xa/1 ml multidoză soluție injectabilă | not available | 10303/2017/03 | ASPEN PHARMA TRADING LIMITED | RO |

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|---------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| FRAXIPARINE 9500 UI anti-factor Xa/1 ml multidoză soluție injectabilă | not available | 10303/2017/04 | ASPEN PHARMA TRADING LIMITED | RO |
| Fraxiparine Multi 9500 U.I. anti-Xa/ 1,0 ml solução injetável | not available | 5742374 | ASPEN PHARMA TRADING LIMITED | PT |
| Fraxiparine Multi 9500 U.I. anti-Xa/ 1,0 ml solução injetável | not available | 5742366 | ASPEN PHARMA TRADING LIMITED | PT |
| Nadroparin calcium Aspen Forte 11,400 I.U. anti-Xa/0.6ml solution for injection in a pre-filled syringe | DE/H/4763/001 | PA 1691/019/001 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin calcium Aspen Forte 15,200 I.U. anti-Xa/0.8ml solution for injection in a pre-filled syringe | DE/H/4763/002 | PA 1691/019/002 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin calcium Aspen 9,500 I.U. anti-Xa/ 1.0 ml solution for injection in a vial | DE/H/4770/002 | PA 1691/021/002 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin calcium Aspen 9,500 I.U. anti-Xa/ 1.0 ml solution for injection in a vial | DE/H/4770/001 | PA 1691/021/001 | ASPEN PHARMA TRADING LIMITED | IE |

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| Nadroparin calcium Aspen Forte 19,000 I.U. anti-Xa/ml solution for injection in a pre-filled syringe | DE/H/4763/003 | PA 1691/019/003 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin Calcium Aspen 5,700 I.U. anti-Xa/ 0.6 ml solution for injection in a pre-filled syringe | DE/H/4762/004 | PA 1691/020/003 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin calcium Aspen 2,850 I.U. anti-Xa/ 0.3 ml solution for injection in a pre-filled syringe | DE/H/4762/002 | PA 1691/020/001 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin Calcium Aspen 7,600 I.U. anti-Xa/ 0.8 ml solution for injection in a pre-filled syringe | DE/H/4762/005 | PA 1691/020/004 | ASPEN PHARMA TRADING LIMITED | IE |
| Nadroparin Calcium Aspen 3,800 I.U. anti-Xa/ 0.4 ml solution for injection in a pre-filled syringe | DE/H/4762/003 | PA 1691/020/002 | ASPEN PHARMA TRADING LIMITED | IE |
| SELEPARINA 3.800 U.I. antiXa/0,4 ml soluzione iniettabile | not available | 026738195 | ITALFARMACO S.P.A | IT |

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|-----------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738260 | ITALFARMACO S.P.A | IT |
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738207 | ITALFARMACO S.P.A | IT |
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738219 | ITALFARMACO S.P.A | IT |
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738221 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738233 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738245 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738258 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738272 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738284 | ITALFARMACO S.P.A | IT |

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| SELEPARINA 2.850 U.I. antiXa/0,3 ml soluzione iniezzabile | not available | 026738183 | ITALFARMACO S.P.A | IT |
| SELEDIE 15.200 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 034668133 | ITALFARMACO S.P.A | IT |
| SELEDIE 19.000 U.I. antiXa/1 ml soluzione iniezzabile | not available | 034668160 | ITALFARMACO S.P.A | IT |
| SELEDIE 11.400 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 034668107 | ITALFARMACO S.P.A | IT |
| SELEDIE 15.200 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 034668145 | ITALFARMACO S.P.A | IT |
| SELEDIE 19.000 U.I. antiXa/1 ml soluzione iniezzabile | not available | 034668172 | ITALFARMACO S.P.A | IT |
| SELEDIE 15.200 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 034668158 | ITALFARMACO S.P.A | IT |
| SELEDIE 19.000 U.I. antiXa/1 ml soluzione iniezzabile | not available | 034668184 | ITALFARMACO S.P.A | IT |
| SELEDIE 11.400 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 034668119 | ITALFARMACO S.P.A | IT |

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|-----------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| SELEDIE 11.400 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 034668121 | ITALFARMACO S.P.A | IT |
| SELEDIE 11.400 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 034668018 | ITALFARMACO S.P.A | IT |
| SELEDIE 15.200 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 034668044 | ITALFARMACO S.P.A | IT |
| SELEDIE 19.000 U.I. antiXa/1 ml soluzione iniezzabile | not available | 034668071 | ITALFARMACO S.P.A | IT |
| SELEPARINA 2.850 U.I. antiXa/0,3 ml soluzione iniezzabile | not available | 026738017 | ITALFARMACO S.P.A | IT |
| SELEPARINA 3.800 U.I. antiXa/0,4 ml soluzione iniezzabile | not available | 026738056 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738132 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738082 | ITALFARMACO S.P.A | IT |
| SELEPARINA 7.600 U.I. antiXa/0,8 ml soluzione iniezzabile | not available | 026738094 | ITALFARMACO S.P.A | IT |

| 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 |
|-----------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738120 | ITALFARMACO S.P.A | IT |
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738068 | ITALFARMACO S.P.A | IT |
| SELEPARINA 5.700 U.I. antiXa/0,6 ml soluzione iniezzabile | not available | 026738070 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738144 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738106 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/1 ml soluzione iniezzabile | not available | 026738118 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/ml soluzione iniezzabile | not available | 026738169 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/ml soluzione iniezzabile | not available | 026738157 | ITALFARMACO S.P.A | IT |
| SELEPARINA 9.500 U.I. antiXa/ml soluzione iniezzabile | not available | 026738171 | ITALFARMACO S.P.A | IT |