



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 May 2025  
EMA/185276/2025  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): alfentanil

Procedure No. PSUSA/00000082/202409



| 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 |
|-------------------------------------------------------|------------------------------|-------------------------------|-------------------------------------|------------------------------------------|
| ALFENTANIL PIRAMAL<br>0,5 mg/ml soluzione iniettabile | not available                | 028348011                     | PIRAMAL CRITICAL CARE<br>ITALIA SPA | IT                                       |
| LIMIFEN 0,5 mg/ml<br>solución inyectable              | not available                | 57.471                        | PIRAMAL CRITICAL CARE<br>B.V.       | ES                                       |
| RAPIFEN 0,5 mg/ml<br>injekční roztok                  | not available                | 05/156/87-C                   | PIRAMAL CRITICAL CARE<br>B.V.       | CZ                                       |
| Rapifen 0,5 mg/ml<br>injeksjonsvæske,<br>oppløsning.  | not available                | 7349                          | PIRAMAL CRITICAL CARE<br>B.V.       | NO                                       |
| Rapifen 0,5 mg/ml<br>injektioneste, liuos             | not available                | 9427                          | PIRAMAL CRITICAL CARE<br>B.V.       | FI                                       |
| Rapifen 0,5 mg/ml<br>Injektionslösung                 | not available                | BE121956                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>Injektionslösung                 | not available                | BE121965                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>Injektionslösung                 | not available                | 2004028020                    | PIRAMAL CRITICAL CARE<br>B.V.       | LU                                       |
| Rapifen 0,5 mg/ml<br>Injektionslösung                 | not available                | 2004028019                    | PIRAMAL CRITICAL CARE<br>B.V.       | LU                                       |
| Rapifen 0,5 mg/ml<br>injektionsvätska, lösning        | not available                | 9427                          | PIRAMAL CRITICAL CARE<br>B.V.       | FI                                       |
| Rapifen 0,5 mg/ml<br>injektionsvätska, lösning        | not available                | 11015                         | PIRAMAL CRITICAL CARE<br>B.V.       | SE                                       |
| Rapifen 0,5 mg/ml<br>oplossing voor injectie          | not available                | BE121956                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>oplossing voor injectie          | not available                | BE121965                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>solution injectable              | not available                | BE121956                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>solution injectable              | not available                | BE121965                      | PIRAMAL CRITICAL CARE<br>B.V.       | BE                                       |
| Rapifen 0,5 mg/ml<br>solution injectable              | not available                | 2004028020                    | PIRAMAL CRITICAL CARE<br>B.V.       | LU                                       |
| Rapifen 0,5 mg/ml                                     | not available                | 2004028019                    | PIRAMAL CRITICAL CARE               | 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 |
|---------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| solution injectable                                           |                              |                               | B.V.                               |                                          |
| Rapifen 1 mg – Ampullen                                       | not available                | 1-18255                       | PIRAMAL CRITICAL CARE B.V.         | AT                                       |
| RAPIFEN 1 mg (0,5 mg/ml), solution injectable                 | not available                | 34009 554 605 7 2             | PIRAMAL CRITICAL CARE B.V.         | FR                                       |
| Rapifen 1 mg/2 ml solução injetável                           | not available                | 8640409                       | PIRAMAL CRITICAL CARE B.V.         | PT                                       |
| Rapifen 5 mg – Ampullen                                       | not available                | 1-18256                       | PIRAMAL CRITICAL CARE B.V.         | AT                                       |
| RAPIFEN 5 mg (0,5 mg/ml), solution injectable                 | not available                | 34009 554 606 3 3             | PIRAMAL CRITICAL CARE B.V.         | FR                                       |
| RAPIFEN 5 mg (0,5 mg/ml), solution injectable                 | not available                | 34009 554 608 6 2             | PIRAMAL CRITICAL CARE B.V.         | FR                                       |
| Rapifen 5 mg/10 ml solução injetável                          | not available                | 8640417                       | PIRAMAL CRITICAL CARE B.V.         | PT                                       |
| Rapifen 500 micrograms/ml, solution for injection or infusion | not available                | PA22583/001/001               | PIRAMAL CRITICAL CARE B.V.         | IE                                       |
| Rapifen oplossing voor injectie 0,5 mg/ml.                    | not available                | RVG 09860                     | PIRAMAL CRITICAL CARE B.V.         | NL                                       |
| Rapifen solution for injection or infusion                    | not available                | PL 37071/0003                 | PIRAMAL CRITICAL CARE LIMITED      | XI                                       |
| RAPIFEN, 0,5 mg/ml Injektionslösung                           | not available                | 2888.00.00                    | PIRAMAL CRITICAL CARE B.V.         | DE                                       |
| Rapifen, injektionsvæske, opløsning                           | not available                | 11106                         | PIRAMAL CRITICAL CARE B.V.         | DK                                       |
| Rapifen® Intensive Care                                       | not available                | PL 37071/0005                 | PIRAMAL CRITICAL CARE LIMITED      | XI                                       |