



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 July 2022  
EMA/724645/2022  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): tapentadol

Procedure No. PSUSA/00002849/202111



| <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> |
|--|-------------------------------------|--------------------------------------|---|---|
| Ationdo 100 mg film-coated tablets             | DE/H/2021/003                       | PL 50414/0004                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo 100 mg filmdragerade tabletter         | DE/H/2021/003                       | 61512                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo 50 mg filmdragerade tabletter          | DE/H/2021/004                       | 61510                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo 75 mg film-coated tablets              | DE/H/2021/002                       | PL 50414/0003                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo 75 mg filmdragerade tabletter          | DE/H/2021/002                       | 61511                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 100 mg depottabletter            | DE/H/2021/005                       | 61514                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 150 mg depottabletter            | DE/H/2021/006                       | 61515                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 200 mg depottabletter            | DE/H/2021/007                       | 61516                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 25 mg depottabletter             | DE/H/2021/009                       | 61518                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 250 mg depottabletter            | DE/H/2021/008                       | 61517                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo Depot 50 mg depottabletter             | DE/H/2021/004                       | 61513                                | GRÜNENTHAL GMBH                           | SE  |
| Ationdo® 50 mg film-coated tablets             | DE/H/2021/001                       | PL 50414/0001                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo® SR 100 mg prolonged-release tablets   | DE/H/2021/005                       | PL 50414/0006                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo® SR 150 mg prolonged-release tablets   | DE/H/2021/006                       | PL 50414/0007                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo® SR 200 mg prolonged-release tablets   | DE/H/2021/007                       | PL 50414/0008                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo® SR 25 mg prolonged-release            | DE/H/2021/009                       | PL 50414/0004                        | GRÜNENTHAL PHARMA LTD.                    | XI  |

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| tablets  |                                     |                                      |   |   |
| Ationdo® SR 250 mg prolonged-release tablets   | DE/H/2021/008                       | PL 50414/0009                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Ationdo® SR 50 mg prolonged-release tablets    | DE/H/2021/004                       | PL 50414/0005                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Palexia 20 mg/ml soluzione orale               | DE/H/2020/011                       | 041571023                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Palexia 20 mg/ml soluzione orale               | DE/H/2020/011                       | 041571035                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Palexia 100 mg – Filmtabletten                 | DE/H/2020/003                       | 1-31063                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 041571086                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 041571098                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423244                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422368                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423271                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422356                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422343                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422279                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg                                 | DE/H/2020/003                       | 040422293                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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| compresse rivestite con film                   |                                     |                                      |   |   |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423220                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422317                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422305                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422281                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422267                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423206                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422331                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423182                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423194                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423257                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040422255                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film    | DE/H/2020/003                       | 040423232                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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| PALEXIA 100 mg compresse rivestite con film         | DE/H/2020/003                       | 040422329                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film         | DE/H/2020/003                       | 040423269                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg compresse rivestite con film         | DE/H/2020/003                       | 040423218                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 100 mg comprimés pelliculés                 | DE/H/2020/003                       | BE382821                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 100 mg comprimés pelliculés                 | DE/H/2020/003                       | 2010110041                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA 100 mg comprimidos recubiertos con película | DE/H/2020/003                       | 73239                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia 100 mg comprimidos revestidos por película  | DE/H/2020/003                       | 5334412                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 100 mg comprimidos revestidos por película  | DE/H/2020/003                       | 5334404                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 100 mg comprimidos revestidos por película  | DE/H/2020/003                       | 5334370                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 100 mg film-coated tablets                  | DE/H/2020/003                       | PA 2242/012/003                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia 100 mg filmdragerade tabletter              | DE/H/2020/003                       | 42623                                | GRÜNENTHAL GMBH                           | SE  |
| PALEXIA 100 mg filmom obalené tablety               | DE/H/2020/003                       | 65/0669/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA 100 mg filmom obložene tablete              | DE/H/2020/003                       | HR-H-619235910                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA 100 mg filmomhulde tabletten                | DE/H/2020/003                       | BE382821                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 100 mg filmsko obložene tablete             | DE/H/2020/003                       | H/10/01208/050                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko                              | DE/H/2020/003                       | H/10/01208/051                       | GRÜNENTHAL GMBH                           | SI  |

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| obložene tablete                               |                                     |                                      |   |   |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/052                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/053                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/054                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/055                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/056                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/049                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/057                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/058                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/059                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/060                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/061                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/062                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/063                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/064                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/065                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/066                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/067                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete        | DE/H/2020/003                       | H/10/01208/068                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko                         | DE/H/2020/003                       | H/10/01208/069                       | GRÜNENTHAL GMBH                           | SI  |

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| obložene tablete                                   |                                     |                                      |   |   |
| PALEXIA 100 mg filmsko obložene tablete            | DE/H/2020/003                       | H/10/01208/070                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete            | DE/H/2020/003                       | H/10/01208/071                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg filmsko obložene tablete            | DE/H/2020/003                       | H/10/01208/072                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 100 mg potahované tablety                  | DE/H/2020/003                       | 65/010/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| Palexia 100 mg tablett, filmdrasjert               | DE/H/2020/003/DC                    | 09-6804                              | GRÜNENTHAL GMBH                           | NO  |
| PALEXIA 100 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/003                       | 21255                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA 100 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/003                       | 32856/12-4-2016                      | GRÜNENTHAL GMBH                           | GR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 240 4 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 234 4 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 239 6 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 236 7 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| Palexia 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 237 3 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 232 1 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 235 0 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, comprimé pelliculé                 | DE/H/2020/003                       | 34009 419 233 8 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 100 mg, filmomhulde tabletten              | DE/H/2020/003                       | RVG 110723                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA 20 mg/ml drank                             | DE/H/2020/011                       | BE429712                             | SA GRÜNENTHAL N.V.                        | BE  |
| Palexia 20 mg/ml drank                             | DE/H/2020/011                       | RVG 120266                           | GRÜNENTHAL B.V.                           | NL  |

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| Palexia 20 mg/ml Lösung zum Einnehmen          | DE/H/2020/011                       | 137824                               | GRÜNENTHAL GES. M.B.H.                    | AT  |
| Palexia 20 mg/ml Lösung zum Einnehmen          | DE/H/2020/011                       | 85577.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Palexia 20 mg/ml mikstur, oppløsning           | DE/H/2020/011                       | 11-8506                              | GRÜNENTHAL GMBH                           | NO  |
| PALEXIA 20 mg/ml oral solution                 | DE/H/2020/011                       | PA 2242/012/011                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| PALEXIA 20 mg/ml oral solution                 | DE/H/2020/011                       | PL 50414/0020                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA 20 mg/ml oralna otopina                | DE/H/2020/011                       | HR-H-173293107                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA 20 mg/ml peroralna raztopina           | DE/H/2020/011                       | H/10/01208/074                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 20 mg/ml peroralna raztopina           | DE/H/2020/011                       | H/10/01208/075                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 20 mg/ml perorální roztok              | DE/H/2020/011                       | 65/010/13-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA 20 mg/ml perorálny roztok              | DE/H/2020/011                       | 65/0412/12-S                         | GRÜNENTHAL GMBH                           | SK  |
| Palexia 20 mg/ml Solução oral                  | DE/H/2020/011                       | 5490529                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 20 mg/ml Solução oral                  | DE/H/2020/011                       | 5490511                              | GRÜNENTHAL S.A.                           | PT  |
| PALEXIA 20 mg/ml solución oral                 | DE/H/2020/011                       | 76792                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| PALEXIA 20 mg/ml solution buvable              | DE/H/2020/011                       | BE429712                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 20 mg/ml solution buvable              | DE/H/2020/011                       | 2013040120                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA 20 mg/ml πόσιμο διάλυμα                | DE/H/2020/011                       | 22524                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA 20 mg/ml, solution buvable             | DE/H/2020/011                       | NL44064                              | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 4 mg/ ml drank                         | DE/H/2020/010                       | BE429703                             | SA GRÜNENTHAL N.V.                        | BE  |
| Palexia 4 mg/ml drank                          | DE/H/2020/010                       | RVG 120265                           | GRÜNENTHAL B.V.                           | NL  |
| Palexia 4 mg/ml Lösung zum Einnehmen           | DE/H/2020/010                       | 85576.00.00                          | GRÜNENTHAL GMBH                           | DE  |



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| Palexia 4 mg/ml mikstur, oppløsning            | DE/H/2020/010                       | 11-8505                              | GRÜNENTHAL GMBH                           | NO  |
| PALEXIA 4 mg/ml oral solution                  | DE/H/2020/010                       | PA2242/012/010                       | GRÜNENTHAL PHARMA LTD.                    | IE  |
| PALEXIA 4 mg/ml oral solution                  | DE/H/2020/010                       | PL 50414/0019                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA 4 mg/ml oralna otopina                 | DE/H/2020/010                       | HR-H-177121264                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA 4 mg/ml peroralna raztopina            | DE/H/2020/010                       | H/10/01208/073                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 4 mg/ml perorální roztok               | DE/H/2020/010                       | 65/009/13-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA 4 mg/ml perorálny roztok               | DE/H/2020/010                       | 65/0411/12-S                         | GRÜNENTHAL GMBH                           | SK  |
| Palexia 4 mg/ml Solução oral                   | DE/H/2020/010                       | 5490503                              | GRÜNENTHAL S.A.                           | PT  |
| PALEXIA 4 mg/ml solución oral                  | DE/H/2020/010                       | 76793                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| PALEXIA 4 mg/ml solution buvable               | DE/H/2020/010                       | BE429703                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 4 mg/ml solution buvable               | DE/H/2020/010                       | 2013040119                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA 4 mg/ml soluzione orale                | DE/H/2020/010                       | 041571011                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 4 mg/ml πόσιμο διάλυμα                 | DE/H/2020/010                       | 22497                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA 4 mg/ml πόσιμο διάλυμα                 | DE/H/2020/011                       | 32857/12-4-2016                      | GRÜNENTHAL GMBH                           | GR  |
| PALEXIA 4 mg/ml, solution buvable              | DE/H/2020/010                       | NL44063                              | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| Palexia 50 mg – Filmtabletten                  | DE/H/2020/001                       | 1-31061                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 041571047                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 041571050                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422976                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422065                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422040                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422038                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422127                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422115                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040423079                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422990                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001/DC                    | 040422988                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040423028                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040423055                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film     | DE/H/2020/001                       | 040422026                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con          | DE/H/2020/001                       | 040422053                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| film   |                                     |                                      |   |   |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040423030                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040423016                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040422089                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040422077                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040422014                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040423067                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040422091                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040423042                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg compresse rivestite con film         | DE/H/2020/001                       | 040422103                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 50 mg comprimés pelliculés                 | DE/H/2020/001                       | BE382803                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 50 mg comprimés pelliculés                 | DE/H/2020/001                       | 2010110039                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA 50 mg comprimidos recubiertos con película | DE/H/2020/001                       | 73242                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| PaLEXIA 50 mg comprimidos revestidos por película  | DE/H/2020/001                       | 5334339                              | GRÜNENTHAL S.A.                           | PT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| Palexia 50 mg comprimidos revestidos por película | DE/H/2020/001                       | 5334313                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 50 mg comprimidos revestidos por película | DE/H/2020/001                       | 5334321                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 50 mg film-coated tablets                 | DE/H/2020/001                       | PA 2242/012/001                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia 50 mg film-coated tablets                 | DE/H/2020/001                       | PL 50414/0010                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Palexia 50 mg filmdragerade tabletter             | DE/H/2020/001                       | 42621                                | GRÜNENTHAL GMBH                           | SE  |
| PALEXIA 50 mg filmom obalené tablety              | DE/H/2020/001                       | 65/0667/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA 50 mg filmom obložene tablete             | DE/H/2020/001                       | HR-H-761027271                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA 50 mg filmomhulde tabletten               | DE/H/2020/001                       | BE382803                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/002                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/003                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/004                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/005                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/006                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/007                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/008                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/001                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/009                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/010                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/011                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/012                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/013                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/014                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/015                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/016                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/017                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/018                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/019                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/020                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/021                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/022                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/023                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg filmsko obložene tablete            | DE/H/2020/001                       | H/10/01208/024                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 50 mg potahované tablety                  | DE/H/2020/001                       | 65/008/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| Palexia 50 mg tablett, filmdrasjert               | DE/H/2020/001                       | 09-6802                              | GRÜNENTHAL GMBH                           | NO  |
| PALEXIA 50 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/001                       | 21253                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA 50 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/001                       | 32854/12-4-2016                      | GRÜNENTHAL GMBH                           | GR  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 218 9 6                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 220 3 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 219 5 7                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 222 6 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 217 2 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 251 6 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 216 6 7                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, comprimé pelliculé              | DE/H/2020/001                       | 34009 419 223 2 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 50 mg, filmomhulde tabletten           | DE/H/2020/001                       | RVG 110721                           | GRÜNENTHAL B.V.                           | NL  |
| Palexia 75 mg – Filmtabletten                  | DE/H/2020/002                       | 1-31062                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 041571062                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 041571074                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422180                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423156                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422242                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423081                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422204                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423143                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422141                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422230                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423168                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422216                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422139                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422178                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422192                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423117                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040423170                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con film     | DE/H/2020/002                       | 040422154                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg compresse rivestite con          | DE/H/2020/002                       | 040422166                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| film   |                                     |                                      |   |   |
| PALEXIA 75 mg<br>comprese rivestite con<br>film                    | DE/H/2020/002                       | 040423129                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg<br>comprese rivestite con<br>film                    | DE/H/2020/002                       | 040423105                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg<br>comprese rivestite con<br>film                    | DE/H/2020/002                       | 040423093                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg<br>comprese rivestite con<br>film                    | DE/H/2020/002                       | 040423131                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg<br>comprese rivestite con<br>film                    | DE/H/2020/002                       | 040422228                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA 75 mg<br>comprimés pelliculés                              | DE/H/2020/002                       | BE382812                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 75 mg<br>comprimés pelliculés                              | DE/H/2020/002                       | 2010110040                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA 75 mg<br>comprimidos recubiertos<br>con película           | DE/H/2020/002                       | 73241                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia 75 mg<br>comprimidos revestidos<br>por película            | DE/H/2020/002                       | 5334362                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 75 mg<br>comprimidos revestidos<br>por película            | DE/H/2020/002                       | 5334347                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 75 mg<br>comprimidos revestidos<br>por película            | DE/H/2020/002                       | 5334354                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia 75 mg film-<br>coated tablets                              | DE/H/2020/002                       | PA 2242/012/002                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia 75 mg film-<br>coated tablets                              | DE/H/2020/002                       | PL 50414/0011                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| Palexia 75 mg<br>film <del>drager</del> ade table <del>tt</del> er | DE/H/2020/002                       | 42622                                | GRÜNENTHAL GMBH                           | SE  |



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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 75 mg filmom obalené tablety           | DE/H/2020/002                       | 65/0668/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA 75 mg filmom obložene tablete          | DE/H/2020/002                       | HR-H-578318944                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA 75 mg filmomhulde tabletten            | DE/H/2020/002                       | BE382812                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/026                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/027                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/028                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/029                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/030                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/031                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/032                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/025                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/033                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/034                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/035                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/036                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/037                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/038                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/039                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete         | DE/H/2020/002                       | H/10/01208/040                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/041                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/042                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/043                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/044                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/045                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/046                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/047                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg filmsko obložene tablete            | DE/H/2020/002                       | H/10/01208/048                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA 75 mg potahované tablety                  | DE/H/2020/002                       | 65/009/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| Palexia 75 mg tablett, filmdrasjert               | DE/H/2020/002                       | 09-6803                              | GRÜNENTHAL GMBH                           | NO  |
| PALEXIA 75 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/002                       | 21254                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA 75 mg επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/2020/002                       | 32855/12-4-2016                      | GRÜNENTHAL GMBH                           | GR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 224 9 7                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 229 0 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 227 8 7                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 225 5 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 228 4 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 226 1 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 230 9 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, comprimé pelliculé                 | DE/H/2020/002                       | 34009 419 231 5 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA 75 mg, filmomhulde tabletten              | DE/H/2020/002                       | RVG 110722                           | GRÜNENTHAL B.V.                           | NL  |
| Palexia Akutschmerz 100 mg Filmtabletten          | DE/H/2020/003                       | 75045.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Palexia Akutschmerz 50 mg Filmtabletten           | DE/H/2020/001                       | 75043.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Palexia Akutschmerz 75 mg Filmtabletten           | DE/H/2020/002                       | 75044.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 041571151                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 041571148                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422507                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423422                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422533                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423473                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423408                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422608                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da        | DE/H/2020/005                       | 040422545                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| 100 mg  |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422572                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422495                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423461                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423396                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422519                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422560                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423459                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422558                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423384                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423410                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423446                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422596                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a                               | DE/H/2020/005                       | 040422584                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato da 100 mg                     |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040422521                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 100 mg | DE/H/2020/005                       | 040423434                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 041571175                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 041571163                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422709                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422697                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423562                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422659                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423509                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423523                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423547                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423574                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 40423485                             | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423497                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423535                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423511                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422634                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422673                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422661                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422646                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422723                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040423550                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422711                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422622                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422685                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| 150 mg  |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 150 mg | DE/H/2020/006                       | 040422610                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 041571199                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 041571187                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422848                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423648                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423663                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422800                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422812                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422836                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422798                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422762                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422824                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a                               | DE/H/2020/007                       | 040423675                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato da 200 mg                     |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423624                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422774                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422786                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423586                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423598                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423612                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423651                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422735                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423600                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422747                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040423636                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 200 mg | DE/H/2020/007                       | 040422750                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |



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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423877                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423790                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423788                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423939                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423927                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423840                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423826                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423966                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423992                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423891                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423903                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423915                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg | DE/H/2020/009                       | 040423889                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| mg  |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423980                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423954                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423853                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423838                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423941                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423802                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423978                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423865                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 040423814                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 041571112                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 25 mg  | DE/H/2020/009                       | 041571100                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 041571201                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a                               | DE/H/2020/008                       | 041571213                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato da 250 mg                     |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422949                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422887                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422851                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422863                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423764                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422925                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423752                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423749                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422899                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423713                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422937                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422901                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423737                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423701                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423776                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422964                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422875                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422913                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423699                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423687                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040422952                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 250 mg | DE/H/2020/008                       | 040423725                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg  | DE/H/2020/004                       | 041571136                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg  | DE/H/2020/004                       | 041571124                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg  | DE/H/2020/004                       | 040423307                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| mg   |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422432                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422370                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422457                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423372                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423360                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422420                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423283                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423321                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422394                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423295                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423345                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423333                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a                              | DE/H/2020/004                       | 040422444                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato da 50 mg                     |                                     |                                      |   |   |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422483                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422469                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423319                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422406                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422471                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422382                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040422418                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| PALEXIA compresse a rilascio prolungato da 50 mg | DE/H/2020/004                       | 040423358                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Palexia depot 100 mg depottablett                | DE/H/2020/005                       | 09-6807                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 100 mg depottabletter              | DE/H/2020/005                       | 42625                                | GRÜNENTHAL GMBH                           | SE  |
| Palexia depot 150 mg depottablett                | DE/H/2020/006                       | 09-6808                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 150 mg depottabletter              | DE/H/2020/006                       | 42626                                | GRÜNENTHAL GMBH                           | SE  |
| Palexia depot 200 mg depottablett                | DE/H/2020/007                       | 09-6809                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 200 mg depottabletter              | DE/H/2020/007                       | 42627                                | GRÜNENTHAL GMBH                           | SE  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Palexia depot 25 mg depottablett                   | DE/H/2020/009                       | 11-8344                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 25 mg depottabletter                 | DE/H/2020/009                       | 46138                                | GRÜNENTHAL GMBH                           | SE  |
| Palexia depot 250 mg depottablett                  | DE/H/2020/008                       | 09-6810                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 250 mg depottabletter                | DE/H/2020/008                       | 42628                                | GRÜNENTHAL GMBH                           | SE  |
| Palexia depot 50 mg depottablett                   | DE/H/2020/004                       | 09-6806                              | GRÜNENTHAL GMBH                           | NO  |
| Palexia Depot 50 mg depottabletter                 | DE/H/2020/004                       | 42624                                | GRÜNENTHAL GMBH                           | SE  |
| Palexia Depot, depottabletter, 100 mg              | DE/H/2020/005                       | 45155                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia Depot, depottabletter, 150 mg              | DE/H/2020/006                       | 45156                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia Depot, depottabletter, 200 mg              | DE/H/2020/007                       | 45157                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia Depot, depottabletter, 25 mg               | DE/H/2020/009                       | 48784                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia Depot, depottabletter, 250 mg              | DE/H/2020/008                       | 45158                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia Depot, depottabletter, 50 mg               | DE/H/2020/004                       | 45154                                | GRÜNENTHAL GMBH                           | DK  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 255 1 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 256 8 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 253 9 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 258 0 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération           | DE/H/2020/005                       | 34009 419 252 2 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |

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|--|-------------------------------------|--------------------------------------|---|---|
| prolongée  |                                     |                                      |   |   |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 259 7 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 254 5 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 100 mg, comprimé à libération prolongée | DE/H/2020/005                       | 34009 419 257 4 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 276 9 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 278 1 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 272 3 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 280 6 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 274 6 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 275 2 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 279 8 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 150 mg, comprimé à libération prolongée | DE/H/2020/006                       | 34009 419 277 5 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 285 8 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg,                                 | DE/H/2020/007                       | 34009 419 286 4 2                    | LABORATOIRES                              | FR  |



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|--|-------------------------------------|--------------------------------------|---|---|
| comprimé à libération prolongée                    |                                     |                                      | GRÜNENTHAL S.A.S.                         |   |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 281 2 3                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 282 9 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 288 7 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 284 1 3                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 287 0 3                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 200 mg, comprimé à libération prolongée | DE/H/2020/007                       | 34009 419 283 5 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 947 6 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 947 7 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 947 8 5                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 947 9 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 948 0 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 948 1 5                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 948 2 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 25 mg, comprimé à libération prolongée  | DE/H/2020/009                       | 34009 300 948 3 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 291 8 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 289 3 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 292 4 3                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 290 1 4                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 293 0 4                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 294 7 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 297 6 2                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 250 mg, comprimé à libération prolongée | DE/H/2020/008                       | 34009 419 295 3 3                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée  | DE/H/2020/004                       | 34009 419 246 2 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée  | DE/H/2020/004                       | 34009 419 241 0 1                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération            | DE/H/2020/004                       | 34009 419 245 6 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |

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|--|-------------------------------------|--------------------------------------|---|---|
| prolongée  |                                     |                                      |   |   |
| PALEXIA LP 50 mg, comprimé à libération prolongée          | DE/H/2020/004                       | 34009 419 242 7 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée          | DE/H/2020/004                       | 34009 419 248 5 9                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée          | DE/H/2020/004                       | 34009 419 249 1 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée          | DE/H/2020/004                       | 34009 419 243 3 0                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| PALEXIA LP 50 mg, comprimé à libération prolongée          | DE/H/2020/004                       | 34009 419 247 9 8                    | LABORATOIRES GRÜNENTHAL S.A.S.            | FR  |
| Palexia retard 100 mg – Retardtabletten                    | DE/H/2020/005                       | 1-31065                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA RETARD 100 mg comprimés à libération prolongée     | DE/H/2020/005                       | BE382846                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 100 mg comprimés à libération prolongée     | DE/H/2020/005                       | 2010110043                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA retard 100 mg comprimidos de liberación prolongada | DE/H/2020/005                       | 73244                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia retard 100 mg comprimidos de libertação prolongada | DE/H/2020/005                       | 5334453                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 100 mg comprimidos de libertação prolongada | DE/H/2020/005                       | 5334461                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 100 mg comprimidos de libertação prolongada | DE/H/2020/005                       | 5334479                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 100 mg Retardtabletten                      | DE/H/2020/005                       | 76262.00.00                          | GRÜNENTHAL GMBH                           | DE  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA retard 100 mg tablete s produljenim oslobađanjem   | DE/H/2020/005                       | HR-H-107720962                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 100 mg tabletten met verlengde afgifte      | DE/H/2020/005                       | BE382846                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 100 mg tabletten met verlengde afgifte      | DE/H/2020/005                       | RVG 110728                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 100 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/005                       | 65/0671/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 100 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/005                       | 65/016/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 100 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/005                       | 21257                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA retard 100 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/005                       | 30724/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| Palexia retard 150 mg – Retardtabletten                    | DE/H/2020/006                       | 1-31066                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA RETARD 150 mg comprimés à libération prolongée     | DE/H/2020/006                       | BE382855                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 150 mg comprimés à libération prolongée     | DE/H/2020/006                       | 2010110044                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA retard 150 mg comprimidos de liberación prolongada | DE/H/2020/006                       | 73245                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia retard 150 mg comprimidos de libertação prolongada | DE/H/2020/006                       | 5334503                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 150 mg comprimidos de libertação prolongada | DE/H/2020/006                       | 5334529                              | GRÜNENTHAL S.A.                           | PT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Palexia retard 150 mg comprimidos de libertação prolongada | DE/H/2020/006                       | 5334511                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 150 mg Retardtabletten                      | DE/H/2020/006                       | 76263.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA retard 150 mg tablete s produljenim oslobađanjem   | DE/H/2020/006                       | HR-H-687263718                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 150 mg tabletten met verlengde afgifte      | DE/H/2020/006                       | BE382855                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 150 mg tabletten met verlengde afgifte      | DE/H/2020/006                       | RVG 110729                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 150 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/006                       | 65/0672/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 150 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/006                       | 65/017/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 150 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/006                       | 21258                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA retard 150 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/006                       | 30725/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| Palexia retard 200 mg - Retardtabletten                    | DE/H/2020/007                       | 1-31067                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA RETARD 200 mg comprimés à libération prolongée     | DE/H/2020/007                       | BE382864                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 200 mg comprimés à libération prolongée     | DE/H/2020/007                       | 2010110045                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA retard 200 mg comprimidos de liberación prolongada | DE/H/2020/007                       | 73246                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia retard 200 mg                                      | DE/H/2020/007                       | 5334545                              | GRÜNENTHAL S.A.                           | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| comprimidos de libertação prolongada                       |                                     |                                      |   |   |
| Palexia retard 200 mg comprimidos de libertação prolongada | DE/H/2020/007                       | 5334537                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 200 mg comprimidos de libertação prolongada | DE/H/2020/007                       | 5334552                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 200 mg Retardtabletten                      | DE/H/2020/007                       | 76264.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA retard 200 mg tablete s produljenim oslobađanjem   | DE/H/2020/007                       | HR-H-044989300                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 200 mg tabletten met verlengde afgifte      | DE/H/2020/007                       | BE382864                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 200 mg tabletten met verlengde afgifte      | DE/H/2020/007                       | RVG 110730                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 200 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/007                       | 65/0673/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 200 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/007                       | 65/018/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 200 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/007                       | 21259                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA retard 200 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/007                       | 30726/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| PALEXIA RETARD 25 mg comprimés à libération prolongée      | DE/H/2020/009/DC                    | BE425241                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 25 mg comprimés à libération prolongée      | DE/H/2020/009                       | 2012090063                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA retard 25 mg                                       | DE/H/2020/009                       | 75917                                | GRÜNENTHAL PHARMA S.A.                    | ES  |

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|---|-------------------------------------|--------------------------------------|---|---|
| comprimidos de liberación prolongada                      |                                     |                                      |   |   |
| Palexia retard 25 mg comprimidos de libertação prolongada | DE/H/2020/009                       | 5462957                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 25 mg comprimidos de libertação prolongada | DE/H/2020/009                       | 5462965                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 25 mg Retardtabletten                      | DE/H/2020/009                       | 84738.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA retard 25 mg tablete s produljenim oslobađanjem   | DE/H/2020/009                       | HR-H-411609269                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 25 mg tabletten met verlengde afgifte      | DE/H/2020/009                       | BE425241                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 25 mg tabletten met verlengde afgifte      | DE/H/2020/009                       | RVG 120262                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 25 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/009                       | 65/0225/12-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 25 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/009                       | 65/310/12-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 25 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/009                       | 022295                               | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA retard 25 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/009                       | 30728/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| Palexia retard 250 mg – Retardtabletten                   | DE/H/2020/008                       | 1-31068                              | GRÜNENTHAL GES. M.B.H.                    | AT  |
| PALEXIA RETARD 250 mg comprimés à libération prolongée    | DE/H/2020/008                       | BE382873                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 250 mg comprimés à                         | DE/H/2020/008                       | 2010110046                           | SA GRÜNENTHAL N.V.                        | LU  |

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|--|-------------------------------------|--------------------------------------|---|---|
| libération prolongée                                       |                                     |                                      |   |   |
| PALEXIA retard 250 mg comprimidos de liberación prolongada | DE/H/2020/008                       | 73247                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia retard 250 mg comprimidos de libertação prolongada | DE/H/2020/008                       | 5334560                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 250 mg comprimidos de libertação prolongada | DE/H/2020/008                       | 5334602                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 250 mg comprimidos de libertação prolongada | DE/H/2020/008                       | 5334578                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 250 mg Retardtabletten                      | DE/H/2020/008                       | 76265.00,00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA retard 250 mg tablete s produljenim oslobađanjem   | DE/H/2020/008                       | HR-H-710842589                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 250 mg tabletten met verlengde afgifte      | DE/H/2020/008                       | BE382873                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 250 mg tabletten met verlengde afgifte      | DE/H/2020/008                       | RVG 110731                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 250 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/008                       | 65/0674/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 250 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/008                       | 65/019/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 250 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/008                       | 21260                                | GRÜNENTHAL GMBH                           | CY  |
| PALEXIA retard 250 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/008                       | 30727/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| Palexia retard 50 mg - Retardtabletten                     | DE/H/2020/004                       | 1-31064                              | GRÜNENTHAL GES. M.B.H.                    | AT  |



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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA RETARD 50 mg comprimés à libération prolongée     | DE/H/2020/004                       | BE382837                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA RETARD 50 mg comprimés à libération prolongée     | DE/H/2020/004                       | 2010110042                           | SA GRÜNENTHAL N.V.                        | LU  |
| PALEXIA retard 50 mg comprimidos de liberación prolongada | DE/H/2020/004                       | 73243                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| Palexia retard 50 mg comprimidos de libertação prolongada | DE/H/2020/004                       | 5334420                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 50 mg comprimidos de libertação prolongada | DE/H/2020/004                       | 5334438                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 50 mg comprimidos de libertação prolongada | DE/H/2020/004                       | 5334446                              | GRÜNENTHAL S.A.                           | PT  |
| Palexia retard 50 mg Retardtabletten                      | DE/H/2020/004                       | 76261.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| PALEXIA retard 50 mg tablete s produljenim oslobađanjem   | DE/H/2020/004                       | HR-H-328480033                       | GRÜNENTHAL GMBH                           | HR  |
| PALEXIA RETARD 50 mg tabletten met verlengde afgifte      | DE/H/2020/004                       | BE382837                             | SA GRÜNENTHAL N.V.                        | BE  |
| PALEXIA Retard 50 mg tabletten met verlengde afgifte      | DE/H/2020/004                       | RVG 110724                           | GRÜNENTHAL B.V.                           | NL  |
| PALEXIA retard 50 mg tablety s predĺženým uvoľňovaním     | DE/H/2020/004                       | 65/0670/10-S                         | GRÜNENTHAL GMBH                           | SK  |
| PALEXIA retard 50 mg tablety s prodlouženým uvoľňovaním   | DE/H/2020/004                       | 65/015/11-C                          | GRÜNENTHAL GMBH                           | CZ  |
| PALEXIA retard 50 mg δισκία παρατεταμένης αποδέσμευσης    | DE/H/2020/004                       | 21256                                | GRÜNENTHAL GMBH                           | CY  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA retard 50 mg<br>δισκία παρατεταμένης<br>αποδέσμευσης     | DE/H/2020/004                       | 30723/6-4-2016                       | GRÜNENTHAL GMBH                           | GR  |
| PALEXIA retard, 100 mg,<br>tabletki o przedłużonym<br>uwalnianiu | DE/H/2020/005                       | 18193                                | GRÜNENTHAL GMBH                           | PL  |
| PALEXIA retard, 150 mg,<br>tabletki o przedłużonym<br>uwalnianiu | DE/H/2020/006                       | 18194                                | GRÜNENTHAL GMBH                           | PL  |
| PALEXIA retard, 200 mg,<br>tabletki o przedłużonym<br>uwalnianiu | DE/H/2020/007                       | 18195                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia retard, 25 mg,<br>tabletki o przedłużonym<br>uwalnianiu  | DE/H/2020/009                       | 20417                                | GRÜNENTHAL GMBH                           | PL  |
| PALEXIA retard, 250 mg,<br>tabletki o przedłużonym<br>uwalnianiu | DE/H/2020/008                       | 18196                                | GRÜNENTHAL GMBH                           | PL  |
| PALEXIA retard, 50 mg,<br>tabletki o przedłużonym<br>uwalnianiu  | DE/H/2020/004                       | 18192                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia SR 100 mg<br>prolonged-release<br>tablets                | DE/H/2020/005                       | PA 2242/012/005                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 100 mg<br>prolonged-release<br>tablets                | DE/H/2020/005                       | PL 50414/0015                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 100 mg<br>tablete s podaljšanim<br>sproščanjem        | DE/H/2020/005                       | H/10/01208/125                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg<br>tablete s podaljšanim<br>sproščanjem        | DE/H/2020/005                       | H/10/01208/126                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg<br>tablete s podaljšanim<br>sproščanjem        | DE/H/2020/005                       | H/10/01208/127                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg<br>tablete s podaljšanim                       | DE/H/2020/005                       | H/10/01208/128                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| sproščanjem   |                                     |                                      |   |   |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/129                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/130                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/131                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/145                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/132                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/133                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/134                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/135                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/136                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/137                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/138                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/139                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg                                   | DE/H/2020/005                       | H/10/01208/140                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| tablete s podaljšanim sproščanjem                   |                                     |                                      |   |   |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/141                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/142                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/143                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/144                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/146                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/147                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 100 mg tablete s podaljšanim sproščanjem | DE/H/2020/005                       | H/10/01208/124                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia SR 150 mg prolonged-release tablets         | DE/H/2020/006                       | PA 2242/012/006                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 150 mg prolonged-release tablets         | DE/H/2020/006                       | PL 50414/0016                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/149                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/150                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/151                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/152                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/153                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/154                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/156                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/148                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/155                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/157                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/158                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/159                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/160                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/161                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/162                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/163                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| sproščanjem   |                                     |                                      |   |   |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/171                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/164                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/165                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/166                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/167                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/168                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/169                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 150 mg tablete s podaljšanim sproščanjem | DE/H/2020/006                       | H/10/01208/170                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia SR 200 mg prolonged-release tablets         | DE/H/2020/007                       | PA 2242/012/007                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 200 mg prolonged-release tablets         | DE/H/2020/007                       | PL 50414/0017                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/173                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/174                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg                                   | DE/H/2020/007                       | H/10/01208/175                       | GRÜNENTHAL GMBH                           | SI  |

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| tablete s podaljšanim sproščanjem                   |                                     |                                      |   |   |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/176                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/177                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/178                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/179                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/172                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/180                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/181                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/182                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/183                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/184                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/185                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/186                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/187                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/188                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/189                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/190                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/191                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/192                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/193                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/194                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 200 mg tablete s podaljšanim sproščanjem | DE/H/2020/007                       | H/10/01208/195                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia SR 25 mg prolonged-release tablets          | DE/H/2020/009                       | PA 2242/012/009                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 25 mg prolonged-release tablets          | DE/H/2020/009                       | PL 50414/0013                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/077                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/078                       | GRÜNENTHAL GMBH                           | SI  |



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|--|-------------------------------------|--------------------------------------|---|---|
| sproščanjem  |                                     |                                      |   |   |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/079                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/080                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/081                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/082                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/083                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/076                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/092                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/093                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/094                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/095                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/096                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem | DE/H/2020/009                       | H/10/01208/097                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg                                   | DE/H/2020/009                       | H/10/01208/098                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| tablete s podaljšanim sproščanjem                   |                                     |                                      |   |   |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/099                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/084                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/085                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/086                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/087                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/088                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/089                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/090                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 25 mg tablete s podaljšanim sproščanjem  | DE/H/2020/009                       | H/10/01208/091                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia SR 250 mg prolonged-release tablets         | DE/H/2020/008                       | PA 2242/012/008                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 250 mg prolonged-release tablets         | DE/H/2020/008                       | PL 50414/0018                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/197                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/198                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/199                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/200                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/201                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/202                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/203                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/196                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/204                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/205                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/206                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/207                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/208                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/209                       | GRÜNENTHAL GMBH                           | SI  |

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|---|-------------------------------------|--------------------------------------|---|---|
| sproščanjem   |                                     |                                      |   |   |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/210                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/211                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/212                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/213                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/214                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/215                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/216                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/219                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/217                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 250 mg tablete s podaljšanim sproščanjem | DE/H/2020/008                       | H/10/01208/218                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia SR 50 mg prolonged-release tablets          | DE/H/2020/004                       | PA 2242/012/004                      | GRÜNENTHAL PHARMA LTD.                    | IE  |
| Palexia SR 50 mg prolonged-release tablets          | DE/H/2020/004                       | PL 50414/0014                        | GRÜNENTHAL PHARMA LTD.                    | XI  |
| PALEXIA SR 50 mg                                    | DE/H/2020/004                       | H/10/01208/101                       | GRÜNENTHAL GMBH                           | SI  |

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|--|-------------------------------------|--------------------------------------|---|---|
| tablete s podaljšanim sproščanjem                  |                                     |                                      |   |   |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/105                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/103                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/104                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/106                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/107                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/100                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/108                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/109                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/110                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/111                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/112                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/113                       | GRÜNENTHAL GMBH                           | SI  |

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|--|-------------------------------------|--------------------------------------|---|---|
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/114                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/115                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/116                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/117                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/118                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/119                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/120                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/121                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/122                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/123                       | GRÜNENTHAL GMBH                           | SI  |
| PALEXIA SR 50 mg tablete s podaljšanim sproščanjem | DE/H/2020/004                       | H/10/01208/102                       | GRÜNENTHAL GMBH                           | SI  |
| Palexia, 100 mg, tabletki powlekane                | DE/H/2020/003                       | 18210                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia, 20 mg/ml, roztwór doustny                 | DE/H/2020/011                       | 20901                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia, 4 mg/ml,                                  | DE/H/2020/010                       | 20900                                | GRÜNENTHAL GMBH                           | PL  |

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|---|-------------------------------------|--------------------------------------|---|---|
| roztwór doustny                                     |                                     |                                      |   |   |
| Palexia, 50 mg, tabletki powlekane                  | DE/H/2020/001                       | 18208                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia, 75 mg, tabletki powlekane                  | DE/H/2020/002                       | 18209                                | GRÜNENTHAL GMBH                           | PL  |
| Palexia, filmovertrukne tabletter, 100 mg           | DE/H/2020/003                       | 45153                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia, filmovertrukne tabletter, 50 mg            | DE/H/2020/001                       | 45151                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia, filmovertrukne tabletter, 75 mg            | DE/H/2020/002                       | 45152                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia, oral opløsning, 20 mg/ml                   | DE/H/2020/011                       | 49342                                | GRÜNENTHAL GMBH                           | DK  |
| Palexia, oral opløsning, 4 mg/ml                    | DE/H/2020/010                       | 49341                                | GRÜNENTHAL GMBH                           | DK  |
| Tapentadol Grünenthal 100 mg Filmdabletten          | not available                       | 75051.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal 50 mg Filmdabletten           | not available                       | 75049.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal 75 mg Filmdabletten           | not available                       | 75050.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 100 mg Retardtabletten | not available                       | 76272.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 150 mg Retardtabletten | not available                       | 76273.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 200 mg Retardtabletten | not available                       | 76274.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 25 mg Retardtabletten  | not available                       | 84740.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 250 mg Retardtabletten | not available                       | 76275.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Grünenthal retard 50 mg                  | not available                       | 76271.00.00                          | GRÜNENTHAL GMBH                           | DE  |

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|--|-------------------------------------|--------------------------------------|---|---|
| Retardtabletten  |                                     |                                      |   |   |
| Tapentadol Libra-Pharm 20 mg/ml Lösung zum Einnehmen       | DE/H/2021/011                       | 85579.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm 4 mg/ml Lösung zum Einnehmen        | DE/H/2021/010                       | 85578.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm Akutschmerz 100 mg Filmtabletten    | DE/H/2021/003                       | 75048.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm Akutschmerz 50 mg Filmtabletten     | DE/H/2021/001                       | 75046.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm Akutschmerz 75 mg Filmtabletten     | DE/H/2021/002                       | 75047.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 100 mg Retardtabletten       | DE/H/2021/005                       | 76267.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 150 mg Retardtabletten       | DE/H/2021/006                       | 76268.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 200 mg Retardtabletten       | DE/H/2021/007                       | 76269.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 25 mg Retardtabletten        | DE/H/2021/009                       | 84739.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 250 mg Retardtabletten       | DE/H/2021/008                       | 76270.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| Tapentadol Libra-Pharm retard 50 mg Retardtabletten        | DE/H/2021/004                       | 76266.00.00                          | GRÜNENTHAL GMBH                           | DE  |
| TAPENTADOLO GRÜNENTHAL 100 mg compresse rivestite con film | DE/H/2021/003                       | 041572088                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |



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|---|-------------------------------------|--------------------------------------|---|---|
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 041572090                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428183                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428195                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428207                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428219                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428221                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428245                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040425353                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040425290                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg                                    | DE/H/2021/003                       | 040425264                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|--|-------------------------------------|--------------------------------------|---|---|
| compresse rivestite con film                                     |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425302                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425338                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425276                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425288                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425326                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425365                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040428260                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040428233                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con film | DE/H/2021/003                       | 040425252                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
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| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428272                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040428258                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040425314                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 100 mg<br>compresse rivestite con<br>film | DE/H/2021/003                       | 040425340                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film  | DE/H/2021/001                       | 041572049                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film  | DE/H/2021/001                       | 041572052                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film  | DE/H/2021/001                       | 040425023                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film  | DE/H/2021/001                       | 040425050                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film  | DE/H/2021/001                       | 040425124                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg                                     | DE/H/2021/001                       | 040425997                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| compresse rivestite con film                                    |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040425098                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040428029                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040425985                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040428068                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040425062                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040425011                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040428056                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040428070                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con film | DE/H/2021/001                       | 040425074                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
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| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040428017                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425100                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425112                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425047                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040428031                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425086                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425973                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040425035                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 50 mg<br>compresse rivestite con<br>film | DE/H/2021/001                       | 040428043                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg                                    | DE/H/2021/002                       | 040428118                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| compresse rivestite con film                                    |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428132                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428120                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428144                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428157                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428171                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 041572064                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 041572076                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040428169                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film | DE/H/2021/002                       | 040425136                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425163                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425199                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425237                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425175                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425148                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425201                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425151                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040425225                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con<br>film | DE/H/2021/002                       | 040428082                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg                                    | DE/H/2021/002                       | 040428106                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| compresse rivestite con film  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film     | DE/H/2021/002                       | 040425187                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film     | DE/H/2021/002                       | 040425249                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL 75 mg<br>compresse rivestite con film     | DE/H/2021/002                       | 040428094                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>100 mg compresse a<br>rilascio prolungato | DE/H/2021/005                       | 040428462                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>20 mg/ml soluzione<br>orale               | DE/H/2021/011                       | 041572025                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 041572191                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 041572189                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 040428676                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 040428599                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 040425757                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal<br>200 mg compresse a<br>rilascio prolungato | DE/H/2021/007                       | 040428649                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |



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| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425807                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428587                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425771                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428601                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428652                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425744                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428613                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428664                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428637                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425783                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425821                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425845                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a                     | DE/H/2021/007                       | 040425732                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato   |                                     |                                      |   |   |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425769                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425819                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425795                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040425833                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 200 mg compresse a rilascio prolungato | DE/H/2021/007                       | 040428625                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 20mg/ml soluzione orale                | DE/H/2021/011                       | 041572037                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 25 mg compresse a rilascio prolungato  | DE/H/2021/009                       | 040428877                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 25 mg compresse a rilascio prolungato  | DE/H/2021/009                       | 040428880                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 25 mg compresse a rilascio prolungato  | DE/H/2021/009                       | 040428839                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 25 mg compresse a rilascio prolungato  | DE/H/2021/009                       | 041572138                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 25 mg compresse a rilascio prolungato  | DE/H/2021/009                       | 041572126                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 250 mg compresse a rilascio prolungato | DE/H/2021/008                       | 41572203                             | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 250 mg compresse a                     | DE/H/2021/008                       | 40425961                             | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| rilascio prolungato  |                                     |                                      |   |   |
| Tapentadolo Grünenthal 250 mg compresse a rilascio prolungato    | DE/H/2021/008                       | 40425860                             | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 4 mg/ml soluzione orale                   | DE/H/2021/010                       | 041572013                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapentadolo Grünenthal 75 mg compresse rivestite con film        | DE/H/2021/002                       | 040425213                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 041572140                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 041572153                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425542                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425528                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428474                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428411                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425516                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO  | DE/H/2021/005                       | 040425555                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |

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|---|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 100 mg                |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428447                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428450                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428409                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425579                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425593                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428385                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040428435                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425492                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 100 mg | DE/H/2021/005                       | 040425530                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| 100 mg  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040425567                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040425504                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040428397                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040425605                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040428423                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>100 mg | DE/H/2021/005                       | 040425581                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 041572165                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 041572177                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040425694                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO   | DE/H/2021/006                       | 040425706                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 150 mg                |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040428536                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425720                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425629                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425617                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425670                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425643                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040425718                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040428498                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040428548                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| 150 mg  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040425631                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040425668                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040425682                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040428551                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040425656                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040428486                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040428500                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040428524                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>150 mg | DE/H/2021/006                       | 040428575                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO   | DE/H/2021/006                       | 040428512                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 150 mg                |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 150 mg | DE/H/2021/006                       | 040428563                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428916                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428841                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428892                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428928                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428904                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428955                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428979                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da        | DE/H/2021/009                       | 040428791                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |



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|--|-------------------------------------|--------------------------------------|---|---|
| 25 mg  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428993                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428981                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428866                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428942                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428815                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428967                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428827                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428930                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>25 mg | DE/H/2021/009                       | 040428854                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO  | DE/H/2021/009                       | 040428803                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 25 mg                 |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 25 mg  | DE/H/2021/009                       | 040428789                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 041572215                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428688                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040425896                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040425910                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428765                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428702                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428738                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da        | DE/H/2021/008                       | 040428726                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| 250 mg  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040428740                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425959                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425872                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425908                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425884                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425934                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425946                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040428714                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>250 mg | DE/H/2021/008                       | 040425858                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO   | DE/H/2021/008                       | 040428753                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|---|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 250 mg                |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428690                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040428777                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 250 mg | DE/H/2021/008                       | 040425922                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg  | DE/H/2021/004                       | 041572126                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg  | DE/H/2021/004                       | 041572138                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg  | DE/H/2021/004                       | 040425427                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg  | DE/H/2021/004                       | 040425478                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg  | DE/H/2021/004                       | 040428346                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da        | DE/H/2021/004                       | 040428359                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| 50 mg  |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040425454                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428310                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428296                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428322                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428308                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428334                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428373                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040428284                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse<br>a rilascio prolungato da<br>50 mg | DE/H/2021/004                       | 040425391                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO  | DE/H/2021/004                       | 040425377                            | GRÜNENTHAL ITALIA S.R.L.                  | 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> |
|--|-------------------------------------|--------------------------------------|---|---|
| GRÜNENTHAL compresse a rilascio prolungato da 50 mg                |                                     |                                      |   |   |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425403                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040428361                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425480                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425415                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425439                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425441                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425466                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| TAPENTADOLO<br>GRÜNENTHAL compresse a rilascio prolungato da 50 mg | DE/H/2021/004                       | 040425389                            | GRÜNENTHAL ITALIA S.R.L.                  | IT  |
| Tapimio 100 mg prolonged-release capsules, hard                    | not available                       | PL 49718/0082                        | NEURAXPHARM UK LIMITED                    | XI  |

| <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> |
|---|-------------------------------------|--------------------------------------|---|---|
| Tapimio 150 mg prolonged-release capsules, hard           | not available                       | PL 49718/0083                        | NEURAXPHARM UK LIMITED                    | XI  |
| Tapimio 200 mg prolonged-release capsules, hard           | not available                       | PL 49718/0084                        | NEURAXPHARM UK LIMITED                    | XI  |
| Tapimio 250 mg prolonged-release capsules, hard           | not available                       | PL 49718/0085                        | NEURAXPHARM UK LIMITED                    | XI  |
| Tapimio 50 mg prolonged-release capsules, hard            | not available                       | PL 49718/0081                        | NEURAXPHARM UK LIMITED                    | XI  |
| YANTIL 100 mg comprimidos recubiertos con película        | DE/H/2021/003                       | 73613                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL 20 mg/ml solución oral                             | DE/H/2021/011                       | 76795                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL 4 mg/ml solución oral                              | DE/H/2021/010                       | 76794                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL 50 mg comprimidos recubiertos con película         | DE/H/2021/001                       | 73601                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL 75 mg comprimidos recubiertos con película         | DE/H/2021/002                       | 73616                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL retard 100 mg comprimidos de liberación prolongada | DE/H/2021/005                       | 73641                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL retard 150 mg comprimidos de liberación prolongada | DE/H/2021/006                       | 73629                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL retard 200 mg comprimidos de liberación prolongada | DE/H/2021/007                       | 73639                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL retard 25 mg comprimidos de liberación prolongada  | DE/H/2021/009                       | 75921                                | GRÜNENTHAL PHARMA S.A.                    | ES  |
| YANTIL retard 250 mg                                      | DE/H/2021/008                       | 73630                                | GRÜNENTHAL PHARMA S.A.                    | ES  |

| <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> |
|--|-------------------------------------|--------------------------------------|---|---|
| comprimidos de liberación prolongada                     |                                     |                                      |   |   |
| YANTIL retard 50 mg comprimidos de liberación prolongada | DE/H/2021/004                       | 73624                                | GRÜNENTHAL PHARMA S.A.                    | ES  |