



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 July 2023  
EMA/320303/2023  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): naltrexone

Procedure No. PSUSA/00002117/202211



| <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> |
|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Abernil 50 mg tablets                          | not available                       | 19979                                | MEDOCHEMIE LTD.                           | CY                                              |
| Adepend 50 mg filmom obalené tablety           | AT/H/0339/001                       | 19/0391/10-S                         | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SK                                              |
| Adepend 50 mg filmom obložene tablete          | not available                       | HR-H-653697303                       | AMOMED PHARMA GMBH                        | HR                                              |
| Adepend 50 mg filmom obložene tablete          | not available                       | HR-H-653697303                       | AMOMED PHARMA GMBH                        | HR                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/001                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/002                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/003                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/004                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/005                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmsko obložene tablete         | AT/H/0339/001                       | H/10/00123/006                       | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | SI                                              |
| Adepend 50 mg filmtabletta                     | AT/H/0339/001                       | OGYI-T-21368/03                      | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | HU                                              |
| Adepend 50 mg filmtabletta                     | AT/H/0339/001                       | OGYI-T-21368/02                      | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | HU                                              |
| Adepend 50 mg filmtabletta                     | AT/H/0339/001                       | OGYI-T-21368/01                      | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | HU                                              |
| Adepend 50 mg Filmtabletten                    | AT/H/0339/001                       | 79343.00.00                          | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | DE                                              |
| Adepend 50 mg potahované tablety               | AT/H/0339/001                       | 19/533/10-C                          | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | CZ                                              |
| Adepend, 50 mg, tabletki powlekane             | AT/H/0339/001                       | 17607                                | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH    | PL                                              |
| ANTAXONE 100 mg/20 ml soluzione orale          | not available                       | 025855040                            | ZAMBON ITALIA S.R.L.                      | IT                                              |
| ANTAXONE 50 mg capsule rigide                  | not available                       | 025855077                            | ZAMBON 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> |
|---------------------------------------------------------------------|-------------------------------------|--------------------------------------|----------------------------------------------------------------|-------------------------------------------------|
| ANTAXONE 50 mg/10 ml soluzione orale                                | not available                       | 025855065                            | ZAMBON ITALIA S.R.L.                                           | IT                                              |
| BASINAL® 100mg comprimidos                                          | not available                       | 2053791                              | LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.               | PT                                              |
| BASINAL® 100mg comprimidos                                          | not available                       | 2053692                              | LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.               | PT                                              |
| Dependex 50 mg - Filmdabletten                                      | not available                       | 1-25702                              | AMOMED PHARMA GMBH                                             | AT                                              |
| DESTOXICAN 50 mg COMPRIMIDOS                                        | not available                       | 3875390                              | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A.                  | PT                                              |
| DESTOXICAN 50 mg COMPRIMIDOS                                        | not available                       | 3887593                              | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A.                  | PT                                              |
| DESTOXICAN 50 mg COMPRIMIDOS                                        | not available                       | 5795299                              | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A.                  | PT                                              |
| DESTOXICAN 50 mg COMPRIMIDOS                                        | not available                       | 5795398                              | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A.                  | PT                                              |
| Ethylex 50 mg film-coated tablets.                                  | IE/H/0154/001                       | PA 0934/002/001                      | AOP ORPHAN PHARMACEUTICALS GMBH                                | IE                                              |
| Ethylex 50 mg Filmdabletten                                         | AT/H/0339/001                       | 1-24856                              | ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH                         | AT                                              |
| Naldix 50 mg filmdragerade tabletter                                | FI/H/0781/001                       | 30189                                | POA PHARMA SCANDINAVIA AB                                      | FI                                              |
| Naldix 50 mg tabletti, kalvopäällysteinen                           | FI/H/0781/001                       | 30189                                | POA PHARMA SCANDINAVIA AB                                      | FI                                              |
| NALOREX 50 mg compresse rivestite con film<br>Naltrexone cloridrato | not available                       | 025969039                            | L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A. | IT                                              |
| Naltex, 50 mg, tabletki powlekane                                   | NL/H/1151/001                       | 17612                                | ACCORD HEALTHCARE POLSKA SP. Z O.O.                            | PL                                              |
| Naltrekson aop 50 mg filmsko obložene tablete                       | IE/H/0153/001                       | H/07/01079/001-005                   | AOP ORPHAN PHARMACEUTICALS GMBH                                | SI                                              |
| Naltreksonklorid<br>Amomed 50 mg filmom obložene tablete            | not available                       | HR-H-425331716                       | AMOMED PHARMA GMBH                                             | HR                                              |

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|-------------------------------------------------------------------|---------------|-------------|----------------------------------------------------------------------|----|
| Naltrexon "Accord",<br>filmovertukne tabletter                    | NL/H/1151/001 | 43589       | ACCORD HEALTHCARE B.V.                                               | DK |
| Naltrexon "AOP",<br>filmovertukne tabletter                       | IE/H/0153/001 | 37851       | AOP ORPHAN<br>PHARMACEUTICALS GMBH                                   | DK |
| Naltrexon Accord 50 mg<br>Filmtabletten                           | NL/H/1151/001 | 136748      | ACCORD HEALTHCARE B.V.                                               | AT |
| Naltrexon Accord 50 mg<br>tabletti,<br>kalvopäällysteinen         | NL/H/1151/001 | 25250       | ACCORD HEALTHCARE B.V.                                               | FI |
| Naltrexon HCl aop 50 mg<br>filmomhulde tabletten                  | IE/H/0153/001 | RVG 32392   | AOP ORPHAN<br>PHARMACEUTICALS GMBH                                   | NL |
| Naltrexon HCl aop 50 mg<br>Filmtabletten                          | IE/H/0153/001 | 60422.00.00 | AOP ORPHAN<br>PHARMACEUTICALS GMBH                                   | DE |
| Naltrexon Hydrochloride<br>Accord 50 mg<br>filmomhulde tabletten  | NL/H/1151/001 | RVG 102900  | ACCORD HEALTHCARE B.V.                                               | NL |
| Naltrexon Molteni 50 mg<br>filmdragerade tabletter                | not available | 50662       | L. MOLteni AND C. DEI<br>F.LLI ALITTI SOCIETÀ DI<br>ESERCIZIO S.P.A. | SE |
| Naltrexon Vitaflo 50 mg<br>filmdragerade tabletter                | IE/H/0154/001 | 21067       | AOP ORPHAN<br>PHARMACEUTICALS GMBH                                   | SE |
| Naltrexon Vitaflo 50 mg<br>tabletti,<br>kalvopäällysteinen        | IE/H/0154/001 | 19506       | AOP ORPHAN<br>PHARMACEUTICALS GMBH                                   | FI |
| Naltrexona Accord 50 mg<br>comprimidos revestidos<br>por película | NL/H/1151/001 | 5328760     | ACCORD HEALTHCARE<br>S.L.U.                                          | PT |
| Naltrexona Accord 50 mg<br>comprimidos revestidos<br>por película | NL/H/1151/001 | 5328778     | ACCORD HEALTHCARE<br>S.L.U.                                          | PT |
| Naltrexona Accord 50 mg<br>comprimidos revestidos<br>por película | NL/H/1151/001 | 5328802     | ACCORD HEALTHCARE<br>S.L.U.                                          | PT |
| Naltrexona Accord 50 mg<br>comprimidos revestidos<br>por película | NL/H/1151/001 | 5328810     | ACCORD HEALTHCARE<br>S.L.U.                                          | PT |
| Naltrexona Accord 50 mg<br>comprimidos revestidos<br>por película | NL/H/1151/001 | 5328828     | ACCORD HEALTHCARE<br>S.L.U.                                          | PT |

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| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328836       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328844       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328851       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328869       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328877       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328901       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexona Accord 50 mg comprimidos revestidos por película | NL/H/1151/001 | 5328919       | ACCORD HEALTHCARE S.L.U.                      | PT |
| Naltrexonă Amomed 50 mg comprimate filmate                  | not available | 11940/2019/04 | AMOMED PHARMA GMBH                            | RO |
| Naltrexonă Amomed 50 mg comprimate filmate                  | not available | 11940/2019/01 | AMOMED PHARMA GMBH                            | RO |
| Naltrexonă Amomed 50 mg comprimate filmate                  | not available | 11940/2019/03 | AMOMED PHARMA GMBH                            | RO |
| Naltrexonă Amomed 50 mg comprimate filmate                  | not available | 11940/2019/02 | AMOMED PHARMA GMBH                            | RO |
| NALTREXONA DESTOXICAN 50 mg/20 ml SOLUÇÃO ORAL              | not available | 5772207       | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| NALTREXONA DESTOXICAN 50 mg/20 ml SOLUÇÃO ORAL              | not available | 4085098       | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| NALTREXONA DESTOXICAN 50 mg/20 ml SOLUÇÃO ORAL              | not available | 5470695       | PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A. | PT |
| Naltrexone "POA Pharma", filmovertrukne tabletter           | FI/H/0781/001 | 49645         | POA PHARMA SCANDINAVIA AB                     | DK |

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|-------------------------------------------------------------|---------------|-------------------|---------------------------------|----|
| Naltrexone 50 mg film-coated tablets                        | IE/H/0153/001 | PA 0934/003/001   | AOP ORPHAN PHARMACEUTICALS GMBH | IE |
| Naltrexone Accord 50 mg apvalkotās tabletes                 | NL/H/1151/001 | 10-0357           | ACCORD HEALTHCARE B.V.          | LV |
| Naltrexone Accord 50 mg comprimés pelliculés                | NL/H/1151/001 | BE374674          | ACCORD HEALTHCARE B.V.          | BE |
| Naltrexone Accord 50 mg comprimés pelliculés                | NL/H/1151/001 | BE374665          | ACCORD HEALTHCARE B.V.          | BE |
| Naltrexone Accord 50 mg filmdragerade tabletter             | NL/H/1151/001 | 53117             | ACCORD HEALTHCARE B.V.          | SE |
| Naltrexone Accord 50 mg filmomhulde tabletten               | NL/H/1151/001 | BE374665          | ACCORD HEALTHCARE B.V.          | BE |
| Naltrexone Accord 50 mg filmomhulde tabletten               | NL/H/1151/001 | BE374674          | ACCORD HEALTHCARE B.V.          | BE |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/001  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/002  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/003  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/004  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/005  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg plėvele dengtos tabletės            | NL/H/1151/001 | LT/1/10/2013/006  | ACCORD HEALTHCARE B.V.          | LT |
| Naltrexone Accord 50 mg Επικαλυμμένα με λεπτό υμένιο δισκία | NL/H/1151/001 | 022584            | ACCORD HEALTHCARE S.L.U.        | CY |
| NALTREXONE ACCORD 50 mg, comprimé pelliculé sécable         | not available | 34009 388 579 5 5 | ACCORD HEALTHCARE FRANCE SAS    | FR |
| NALTREXONE ACCORD 50 mg, comprimé pelliculé sécable         | not available | 34009 388 618 0 8 | ACCORD HEALTHCARE FRANCE SAS    | FR |
| NALTREXONE ACCORD 50 mg, comprimé pelliculé sécable         | not available | 34009 388 619 7 6 | ACCORD HEALTHCARE FRANCE SAS    | FR |
| NALTREXONE ACCORD 50 mg, comprimé pelliculé sécable         | not available | 34009 388 583 2 7 | ACCORD HEALTHCARE FRANCE SAS    | FR |

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| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955078 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955092 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955104 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955116 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955128 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955015 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955027 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955039 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955041 | ACCORD HEALTHCARE<br>S.L.U. | IT |
| Naltrexone Accord<br>Healthcare 50 mg<br>compresse rivestite con<br>film | NL/H/1151/001 | 040955054 | ACCORD HEALTHCARE<br>S.L.U. | IT |

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| Naltrexone Accord Healthcare 50 mg compresse rivestite con film | NL/H/1151/001    | 040955066       | ACCORD HEALTHCARE S.L.U.          | IT |
| Naltrexone Accord Healthcare 50 mg compresse rivestite con film | NL/H/1151/001    | 040955080       | ACCORD HEALTHCARE S.L.U.          | IT |
| Naltrexone Accord, 50 mg õhukese polümeerikattega tabletid      | NL/H/1151/001    | 679610          | ACCORD HEALTHCARE B.V.            | EE |
| Naltrexone Accord50 mg filmdrasjerte tabletter                  | NL/H/1151/001    | 15-10760        | ACCORD HEALTHCARE B.V.            | NO |
| Naltrexone AOP 50 mg Potahované tablety                         | IE/H/0153/001    | 19/562/05-C     | AOP ORPHAN PHARMACEUTICALS GMBH   | CZ |
| Naltrexone hydrochloride 50 mg filmcoated tablets               | IE/H/0153/001    | PL 21344/0002   | AOP ORPHAN PHARMACEUTICALS GMBH   | XI |
| Naltrexone Hydrochloride 50 mg film-coated tablets              | NL/H/1151/001/DC | PA 2315/111/001 | ACCORD HEALTHCARE IRELAND LIMITED | IE |
| Naltrexone Hydrochloride 50 mg film-coated tablets              | NL/H/1151/001    | PL 20075/0144   | ACCORD HEALTHCARE LIMITED         | XI |
| Naltrexone POA Pharma 50 mg filmdragerade tabletter             | FI/H/0958/001    | 35412           | POA PHARMA SCANDINAVIA AB         | FI |
| Naltrexone POA Pharma 50 mg filmdragerade tabletter             | FI/H/0958/001    | 56816           | POA PHARMA SCANDINAVIA AB         | SE |
| Naltrexone POA Pharma 50 mg tabletter, filmdrasjerte            | FI/H/0781/001    | 11-8660         | POA PHARMA SCANDINAVIA AB         | NO |
| Naltrexone POA Pharma 50 mg tabletti, kalvopäällysteinen        | FI/H/0958/001    | 35412           | POA PHARMA SCANDINAVIA AB         | FI |
| NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable            | IE/H/0154/001    | NL30392         | VIATRIS SANTE                     | FR |

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|------------------------------------------------------------------|---------------|-------------|----------------------------------------|----|
| Naltrexonhydrochlorid<br>Accord 50 mg<br>Filmtabletten           | NL/H/1151/001 | 95548.00.00 | ACCORD HEALTHCARE B.V.                 | DE |
| Naltrexonhydrochloride<br>50 PCH, filmomhulde<br>tabletten 50 mg | IE/H/0154/001 | RVG 30958   | PHARMACHEMIE B.V                       | NL |
| Tranalex 50 mg<br>comprimidos recubiertos<br>con película EFG    | NL/H/1151/001 | 73938       | ACCORD HEALTHCARE<br>S.L.U.            | ES |
| Налтрексон Акорд 50<br>mg филмирани таблетки                     | NL/H/1151/001 | 20160081    | ACCORD HEALTHCARE<br>POLSKA SP. Z O.O. | BG |