



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 July 2026
EMADOC-1700519818-3320298
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): naltrexone

EURD list No. PSUSA/00002117/202511



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dependex 50 mg – Filmtabletten	not available	1-25702	WALTER RITTER GMBH + CO. KG	AT
Ethylex 50 mg Filmtabletten	AT/H/0339/001	1-24856	WALTER RITTER GMBH + CO. KG	AT
Naltrexon Accord 50 mg Filmtabletten	NL/H/1151/001	136748	ACCORD HEALTHCARE B.V.	AT
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 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
Abernil 50 mg tablets	not available	19979	MEDOCHEMIE LTD.	CY
Adepend 50 mg potahované tablety	AT/H/0339/001	19/533/10-C	WALTER RITTER GMBH + CO. KG	CZ
Naltrexone Walter Ritter 50 mg potahované tablety	IE/H/0153/001	19/562/05-C	WALTER RITTER GMBH + CO. KG	CZ
Adepend 50 mg Filmtabletten	AT/H/0339/001	79343.00.00	WALTER RITTER GMBH + CO. KG	DE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexon HCl Walter Ritter 50 mg Filmtabletten	IE/H/0153/001	60422.00.00	WALTER RITTER GMBH + CO. KG	DE
Naltrexon-HCl neuraxpharm 50 mg Filmtabletten	not available	85614.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Naltrexonhydrochlorid Accord 50 mg Filmtabletten	NL/H/1151/001	95548.00.00	ACCORD HEALTHCARE B.V.	DE
Naltrexon "Accord", filmovertrukne tabletter	NL/H/1151/001	43589	ACCORD HEALTHCARE B.V.	DK
Naltrexon "Walter Ritter" 50 mg, filmovertrukne tabletter	IE/H/0153/001	37851	WALTER RITTER GMBH + CO. KG	DK
Naltrexone "POA Pharma"	FI/H/0781/001	49645	POA PHARMA SCANDINAVIA AB	DK
Naltrexone Accord, 50 mg õhukese polümeerikattega tabletid	NL/H/1151/001	679610	ACCORD HEALTHCARE B.V.	EE
Tranalex 50 mg comprimidos recubiertos con película EFG	NL/H/1151/001	73938	ACCORD HEALTHCARE S.L.U.	ES
Naldix 50 mg filmdragerade tabletter	FI/H/0781/001	30189	POA PHARMA SCANDINAVIA AB	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naldix 50 mg tabletti, kalvopäällysteinen	FI/H/0781/001	30189	POA PHARMA SCANDINAVIA AB	FI
Naltrexon Accord 50 mg tabletti, kalvopäällysteinen	NL/H/1151/001	25250	ACCORD HEALTHCARE B.V.	FI
Naltrexon Walter Ritter 50 mg filmdragerade tabletter	IE/H/0154/001	19506	WALTER RITTER GMBH + CO. KG	FI
Naltrexon Walter Ritter 50 mg kalvopäällysteiset tabletit	IE/H/0154/001	19506	WALTER RITTER GMBH + CO. KG	FI
Naltrexone POA Pharma 50 mg filmdragerade tabletter	FI/H/0958/001	35412	POA PHARMA SCANDINAVIA AB	FI
Naltrexone POA Pharma 50 mg tabletti, kalvopäällysteinen	FI/H/0958/001	35412	POA PHARMA SCANDINAVIA AB	FI
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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
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
NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable	IE/H/0154/001	34009 367 571 5 8	VIATRIS SANTE	FR
NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable	IE/H/0154/001	34009 367 572 1 9	VIATRIS SANTE	FR
NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable	IE/H/0154/001	34009 377 207 4 8	VIATRIS SANTE	FR
NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable	IE/H/0154/001	34009 573 091 5 2	VIATRIS SANTE	FR
NALTREXONE VIATRIS 50 mg, comprimé pelliculé sécable	IE/H/0154/001	34009 367 570 9 7	VIATRIS SANTE	FR
Adepend 50 mg filmom obložene tablete	not available	HR-H-653697303	WALTER RITTER GMBH + CO. KG	HR

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltreksonklorid Walter Ritter 50 mg filmom obložene tablete	not available	HR-H-425331716	WALTER RITTER GMBH + CO. KG	HR
Adepend 50 mg filmtabletta	AT/H/0339/001	OGYI-T-21368/01	WALTER RITTER GMBH + CO. KG	HU
Adepend 50 mg filmtabletta	AT/H/0339/001	OGYI-T-21368/02	WALTER RITTER GMBH + CO. KG	HU
Adepend 50 mg filmtabletta	AT/H/0339/001	OGYI-T-21368/03	WALTER RITTER GMBH + CO. KG	HU
Ethylex 50 mg film-coated tablets.	IE/H/0154/001	PA 25429/002/001	WALTER RITTER GMBH + CO. KG	IE
Naltrexone 50 mg film-coated tablets	IE/H/0153/001	PA25429/001/001	WALTER RITTER GMBH + CO. KG	IE
Naltrexone Hydrochloride 50 mg film-coated tablets	NL/H/1151/001/DC	PA 2315/111/001	ACCORD HEALTHCARE IRELAND LIMITED	IE
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
ANTAXONE 50 mg/10 ml soluzione orale	not available	025855065	ZAMBON ITALIA S.R.L.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
NALOREX 50 mg compresse rivestite con film Naltrexone cloridrato	not available	025969039	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955078	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955092	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955104	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955116	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955128	ACCORD HEALTHCARE S.L.U.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955015	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955027	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955039	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955041	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955054	ACCORD HEALTHCARE S.L.U.	IT
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955066	ACCORD HEALTHCARE S.L.U.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexone Accord Healthcare 50 mg compresse rivestite con film	NL/H/1151/001	040955080	ACCORD HEALTHCARE S.L.U.	IT
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 apvalkotās tabletes	NL/H/1151/001	10-0357	ACCORD HEALTHCARE B.V.	LV
Naltrexon HCl Walter Ritter 50 mg filmomhulde tabletten	IE/H/0153/001	RVG 32392	WALTER RITTER GMBH + CO. KG	NL

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexon Hydrochloride Accord 50 mg filmomhulde tabletten	NL/H/1151/001	RVG 102900	ACCORD HEALTHCARE B.V.	NL
Naltrexonhydrochloride 50 PCH, filmomhulde tabletten 50 mg	IE/H/0154/001	RVG 30958	PHARMACHEMIE BV	NL
Naltrexone Accord 50 mg filmdrasjerte tabletter	NL/H/1151/001	15-10760	ACCORD HEALTHCARE B.V.	NO
Naltrexone POA Pharma 50 mg tabletter, filmdrasjerte	FI/H/0781/001	11-8660	POA PHARMA SCANDINAVIA AB	NO
Adepend, 50 mg, tabletki powlekane	AT/H/0339/001	17607	WALTER RITTER GMBH + CO. KG	PL
Naltex, 50 mg, tabletki powlekane	NL/H/1151/001	17612	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexona Accord 50 mg comprimidos revestidos por película	NL/H/1151/001	5328760	ACCORD HEALTHCARE S.L.U.	PT
Naltrexona Accord 50 mg comprimidos revestidos por película	NL/H/1151/001	5328778	ACCORD HEALTHCARE S.L.U.	PT
Naltrexona Accord 50 mg comprimidos revestidos por película	NL/H/1151/001	5328802	ACCORD HEALTHCARE S.L.U.	PT
Naltrexona Accord 50 mg comprimidos revestidos por película	NL/H/1151/001	5328810	ACCORD HEALTHCARE S.L.U.	PT
Naltrexona Accord 50 mg comprimidos revestidos por película	NL/H/1151/001	5328828	ACCORD HEALTHCARE S.L.U.	PT
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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
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
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
NALTREXONA DESTOXICAN 50 mg/20 ml SOLUÇÃO ORAL	not available	5772207	PENTAFARMA - SOCIEDADE TECNICO-MEDICINAL S.A.	PT
Naltrexona Amomed 50 mg comprimato filmate	not available	11940/2019/03	WALTER RITTER GMBH + CO. KG	RO

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Naltrexona Amomed 50 mg comprimate filmate	not available	11940/2019/02	WALTER RITTER GMBH + CO. KG	RO
Naltrexona Amomed 50 mg comprimate filmate	not available	11940/2019/04	WALTER RITTER GMBH + CO. KG	RO
Naltrexona Walter Ritter 50 mg comprimate filmate	not available	11940/2019/01	WALTER RITTER GMBH + CO. KG	RO
Naltrexon Molteni 50 mg filmdragerade tabletter	not available	50662	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	SE
Naltrexon Vitaflo 50 mg filmdragerade tabletter	IE/H/0154/001	21067	WALTER RITTER GMBH + CO. KG	SE
Naltrexone Accord 50 mg filmdragerade tabletter	NL/H/1151/001	53117	ACCORD HEALTHCARE B.V.	SE
Naltrexone POA Pharma 50 mg filmdragerade tabletter	FI/H/0958/001	56816	POA PHARMA SCANDINAVIA AB	SE
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/001	WALTER RITTER GMBH + CO. KG	SI
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/002	WALTER RITTER GMBH + CO. KG	SI
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/003	WALTER RITTER GMBH + CO. KG	SI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/004	WALTER RITTER GMBH + CO. KG	SI
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/005	WALTER RITTER GMBH + CO. KG	SI
Adepend 50 mg filmsko obložene tablete	AT/H/0339/001	H/10/00123/006	WALTER RITTER GMBH + CO. KG	SI
Naltrekson Walter Ritter 50 mg filmsko obložene tablete	IE/H/0153/001	H/07/01079/005	WALTER RITTER GMBH + CO. KG	SI
Adepend 50 mg filmom obalené tablety	AT/H/0339/001	19/0391/10-S	WALTER RITTER GMBH + CO. KG	SK
Adepend 50 mg filmcoated tablets	AT/H/0339/001	PL 40311/0003	WALTER RITTER GMBH + CO. KG	XI
Naltrexone Hydrochloride 50 mg film-coated tablets	NL/H/1151/001	PL 20075/0144	ACCORD HEALTHCARE LIMITED	XI
Naltrexone hydrochloride 50 mg film-coated tablets	IE/H/0153/001	PL 40311/0002	WALTER RITTER GMBH + CO. KG	XI