



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 July 2016
EMA/437327/2016
Procedure Management and Committees Support Division

List of nationally authorised medicinal products

Active substance: naltrexone

Procedure no.: PSUSA/00002117/201511



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
Antaxon		OGYI-T-7922/01	Zambon S.P.A.	Hungary
Antaxon		OGYI-T-7922/02 \$ OGYI-T-7922/03	Zambon S.P.A.	Hungary
Antaxone		025855026	Zambon Italia S.R.L.	Italy
Antaxone		025855040 \$ 025855065	Zambon Italia S.R.L.	Italy
Antaxone		025855053 \$ 025855077	Zambon Italia S.R.L.	Italy
Antaxone		2064889 \$ 2160489 \$ 2186385 \$ 2316784 \$ 2432789	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Antaxone		2146785	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Nalorex		0095/29-10-2013	Vianex S.A.	Greece
Nalorex		BE145406	Bristol-Myers Squibb Belgium Nv	Belgium
Nalorex		PL 11184/0104	Bristol-Myers Squibb Pharmaceuticals Limited	United Kingdom
Nemexin		34635.00.00	Bristol-Myers Squibb Gmbh & Co. Kgaa	Germany
ReVia 50 mg Filmtabletten		1-18743	Chiesi Pharmaceuticals Gmbh	Austria
Revia 50 mg filmsko obložene tablete		5363-I-2422/12	Chiesi Pharmaceuticals Gmbh	Slovenia
Revia		61.797	Bristol-Myers Squibb Sa	Spain

Revia		34009 341 751 6 9	Bristol-Myers Squibb	France
Nalorex		0457/07129600	Bristol-Myers Squibb Belgium S.A.	Luxembourg
Nalorex		PA 0002/070/001	Bristol-Myers Squibb Pharmaceuticals Limited	Ireland
Nalorex		025969039	L. Molteni And C. Dei F.Lli Alitti Società Di Esercizio S.P.A.	Italy