



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2024
EMA/94832/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): nalbuphine

Procedure No. PSUSA-00002110-202305



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
Lapainol 10 mg/ml solution for injection	NL/H/0983/001	PA 1353/002/001	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	IE
NALBUFINE HCL ORPHA 10 mg/ml oplossing voor injectie	NL/H/0983/001	RVG 30852	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	NL
Nalbuphin Amomed 10 mg/ml Injektionslösung	not available	1-26798	AMOMED PHARMA GMBH	AT
Nalbuphin Orpha, 10 mg/ml injekční roztok	NL/H/0983/001	65/622/07-C	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	CZ
NALBUPHINE RENAUDIN 20 mg/2 ml, solution injectable	not available	34009 358 314 3 9	LABORATOIRE RENAUDIN	FR
NALBUPHINE RENAUDIN 20 mg/2 ml, solution injectable	not available	34009 358 316 6 8	LABORATOIRE RENAUDIN	FR
NALBUPHINE RENAUDIN 20 mg/2 ml, solution injectable	not available	34009 358 317 2 9	LABORATOIRE RENAUDIN	FR
NALBUPHINE RENAUDIN 20 mg/2 ml, solution injectable	not available	34009 563 733 4 5	LABORATOIRE RENAUDIN	FR
NALBUPHINE RENAUDIN 20 mg/2 ml, solution injectable	not available	34009 563 734 0 6	LABORATOIRE RENAUDIN	FR
NALBUPHINE SERB 20 mg/2 ml, solution injectable	not available	368 941-0	SERB	FR
NALBUPHINE SERB 20 mg/2 ml, solution injectable	not available	358 318-9	SERB	FR
NALPAIN 10 mg / ml ενέσιμο διάλυμα	NL/H/0983/001	70144/4-10-2012	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	GR
NALPAIN 10 mg/ml Injektionslösung	NL/H/0983/001	68103.00.00	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	DE
NALPAIN 10 mg/ml oldatos injekció	NL/H/0983/001	OGYI-T-22407/01	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	HU

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
Nalpain 10 mg/ml raztopina za injiciranje	NL/H/0983/001	H/08/01078/001	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	SI
NALPAIN 10 mg/ml, roztwór do wstrzykiwań	NL/H/0983/001	14424	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	PL
NALPAIN 20 mg/2 ml solution injectable	NL/H/0983/001	382 077-8	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	FR
Nubain 10 mg/ml Injektionslösung	DE/H/6001/001	140200	ALTAMEDICS GMBH	AT
Nubain 10 mg/ml Injektionslösung	DE/H/6001/001	2202453.00.00	ALTAMEDICS GMBH	DE
Nubain 10 mg/ml oplossing voor injectie	DE/H/6001/001	RVG 124338	ALTAMEDICS GMBH	NL