



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/PRAC/75089/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): propranolol (except for centrally authorised product)

Procedure No.: PSUSA/00010251/202106



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
INDERAL 40 mg compresse	not available	A.I.C 020854030	ASTRAZENECA S.P.A.	IT
INDERAL 40 mg compresse.	not available	020854028	ASTRAZENECA S.P.A.	IT
Inderal 10 mg tableter	not available	7724	ASTRAZENECA AB	SE
Inderal 40 mg tableter	not available	7725	ASTRAZENECA AB	SE
Dociton® 10 mg Filmtabletten	not available	6328947.02.00	MIBE GMBH ARZNEIMITTEL	DE
Dociton® 40 mg Filmtabletten	not available	6328947.01.00	MIBE GMBH ARZNEIMITTEL	DE
Dociton® 80 mg Filmtabletten	not available	6328947.00.00	MIBE GMBH ARZNEIMITTEL	DE
Obsidan 40 mg Tabletten	not available	3000860.00.00	PUREN PHARMA GMBH & CO. KG	DE
INDERAL 10 mg, comprimé pelliculé	not available	0173/07099452	ASTRAZENECA S.A. / N.V.	LU
INDERAL 40 mg, comprimé pelliculé	not available	0173/07099453	ASTRAZENECA S.A. / N.V.	LU
AVLOCARDYL 40 mg, comprimé sécable	not available	34009 300 897 6 7	ATNAHS PHARMA NETHERLANDS B.V.	FR
AVLOCARDYL 40 mg, comprimé sécable	not available	34009 372 016 6 7	ATNAHS PHARMA NETHERLANDS B.V.	FR
AVLOCARDYL 40 mg, comprimé sécable	not available	34009 559 175 0 2	ATNAHS PHARMA NETHERLANDS B.V.	FR
Propranolol HCl Aurobindo 40 mg, filmomhulde tabletten	not available	RVG 13599	AUROBINDO PHARMA B.V.	NL
Propranolol HCl Aurobindo 80 mg, filmomhulde tabletten	not available	RVG 13600	AUROBINDO PHARMA B.V.	NL
Half Beta - Prograne 80mg Sustained Release Capsules	not available	PL 11311/0017	TILLOMED LABORATORIES LTD	XI
Propranolol hydrochloride 5mg/5ml Oral Solution	not available	PL 39307/0059	SYRI LIMITED T/A THAME LABORATORIES	XI
Propranolol hydrochloride 50mg/5ml Oral Solution	not available	PL 39307/0062	SYRI LIMITED T/A THAME LABORATORIES	XI
Propranolol Thame 50mg/5ml Oral Solution	MT/H/0411/004	MA1296/01904	SYRI PHARMA LIMITED	MT
Propranolol Thame 5mg/5ml Oral Solution	MT/H/0411/002	MA1296/01901	SYRI PHARMA LIMITED	MT
Obsidan 100 mg	not available	3000865.00.00	PUREN PHARMA GMBH & CO. KG	DE
Propranolol 40mg Tablets	not available	PL 00289/0169	TEVA UK LIMITED	XI
Propranolol 10 mg Tablets	not available	PL 00289/0168	TEVA UK LIMITED	XI
Obsidan 25 mg Tabletten	not available	3000857.00.00	PUREN PHARMA GMBH & CO. KG	DE
Inderal 10 mg - Filmtabletten	not available	13.294	ASTRAZENECA OSTERREICH GMBH	AT

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
Inderal 40 mg - Filmtabletten	not available	13.295	ASTRAZENECA OSTERREICH GMBH	AT
PROPRANOLOL RATIOPHARM L P 160 mg, gélule à libération prolongée	not available	NL13975	TEVA SANTÉ	FR
Beta-Prograne 160mg Sustained Release Capsules.	not available	PL 11311/0001	TILLOMED LABORATORIES LTD	XI
Inderal 10 mg film-coated tablets.	not available	PL 43252/0036	ATNAHS PHARMA UK LIMITED	XI
Inderal 40 mg film-coated tablets.	not available	PL 43252/0037	ATNAHS PHARMA UK LIMITED	XI
INDERAL 10 mg, filmomhulde tablet	not available	BE078897	ASTRAZENECA S.A. / N.V.	BE
INDERAL 40 mg, filmomhulde tablet	not available	BE078881	ASTRAZENECA S.A. / N.V.	BE
Dociton® 160 mg retard Hartkapseln, retardiert	not available	9389.00.00	MIBE GMBH ARZNEIMITTEL	DE
Dociton® 80 mg retard Hartkapseln, retardiert	not available	9389.01.00	MIBE GMBH ARZNEIMITTEL	DE
Bedranol (Propranolol Hydrochloride) SR Capsules 80mg	not available	PL 04416/0320	SANDOZ LTD	XI
Bedranol (Propranolol Hydrochloride) SR Capsules 160mg	not available	PL 04416/0068	SANDOZ LTD	XI
Sumial 10 mg comprimidos recubiertos con película.	not available	42.504	ATNAHS PHARMA NETHERLANDS B.V.	ES
Sumial 40 mg comprimidos recubiertos con película.	not available	42.506	ATNAHS PHARMA NETHERLANDS B.V.	ES
Inderal 10 mg comprimidos revestidos	not available	8168047	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Inderal 40 mg comprimidos revestidos	not available	8168013	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Inderal 40 mg comprimidos revestidos	not available	4545588	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Inderal 10 mg comprimidos revestidos	not available	4545489	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Inderal 10 mg comprimidos revestidos	not available	5903380	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Inderal 10 mg comprimidos revestidos	not available	8168005	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Inderal 40 mg comprimidos	not available	5903489	ASTRAZENECA PRODUTOS	PT

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revestidos			FARMACEUTICOS LDA.	
Dociton® Injektionslösung 1mg/ml	not available	11324.00.00	MIBE GMBH ARZNEIMITTEL	DE
INDERAL δισκία 40mg	not available	37765/07/16.07.2008	ASTRAZENECA S.A	GR