10 June 2021
EMA/382258/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tetrabenazine

Procedure no.: PSUSA/00002911/202010

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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
Nitoman 25 mg comprimidos	not available	70.142	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	ES
Nitoman 25 mg Tablets	not available	PA22698/022/001	BAUSCH HEALTH IRELAND LIMITED	IE
Nitoman 25 mg Tabletten	not available	58924.00.00	HORMOSAN PHARMA GMBH	DE
Nitoman, tabletter	not available	06317	MEDILINK A/S	DK
Nitoman, tabletter	not available	06317	MEDILINK A/S	DK
Tetrabenazina SUN 12,5 mg compresse	NL/H/3504/001	044251015	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Tetrabenazine SUN 12,5 mg tabletten	NL/H/3504/001	RVG 117367	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Tetrabenazin-neuraxpharm 12,5 mg Tabletten	NL/H/3504/001	95282.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Xenazina 25 mg compresse	not available	036688012	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	IT
Xenazine 25 mg tablete	FI/H/0810/001	H/14/01677/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SI
Xenazine 25 mg tabletit	FI/H/0810/001	31115	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	FI
Xenazine 25 mg tabletter	not available	19824	MEDILINK A/S	SE
Xenazine 25 mg δισκία	FI/H/0810/001	3037901	BAUSCH HEALTH IRELAND LIMITED	GR
XENAZINE 25 mg, comprimé sécable	not available	34009 369 319 1 6	SERB	FR