



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 June 2017
EMA/366993/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tetrabenazine

Procedure No.: PSUSA/00002911/201610



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	70142	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	ES
Nitoman 25 mg Tablets	not available	PA 1703/1/1	LUNDBECK UK LLP	IE
Nitoman 25 mg Tabletten	not available	58924.00.00	HORMOSAN PHARMA GMBH	DE
Nitoman, tableter	not available	06317	MEDILINK A/S	DK
Tetrabenazine 12.5 mg tablets	NL/H/3504/001	PL 31750/0063	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Tetrabenazine 25 mg Tablets Xenazine® 25	not available	PL 39386/0001	LUNDBECK UK LLP	UK
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/DC	95282.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Xenazina 25 mg compresse	not available	036688012	CHIESI FARMACEUTICI S.P.A.	IT
Xenazine 25 mg comprimato	FI/H/0810/001	7851/2015/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	RO
Xenazine 25 mg tabletit	FI/H/0810/001	31115	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	FI
Xenazine 25 mg tablets	FI/H/0810/001	H/14/01677/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SI
Xenazine 25 mg tableter	not available	19824	MEDILINK A/S	SE
Xenazine 25 mg δισκία	FI/H/0810/001	49649/13.06.2014	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	GR
Xenazine 25 mg, comprimé sécable	not available	3400936931916	EUSA PHARMA (UK) LIMITED	FR
Xenazine 25 mg, comprimé sécable	not available	3400936931916	EUSA PHARMA (UK) LIMITED	FR