



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2024
EMA/275409/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tetrabenazine

Procedure no.: PSUSA/00002911/202310

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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	BAUSCH HEALTH IRELAND LIMITED	ES
Nitoman 25 mg Tablets	not available	PA22698/022/001	BAUSCH HEALTH IRELAND LIMITED	IE
Nitoman, tableter	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 12.5 mg tablets	NL/H/3504/001	PL 31750/0063	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Tetrabenazine 25 mg Tablets Xenazine® 25	not available	PL 52637/0008	BAUSCH HEALTH IRELAND LIMITED	XI
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

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
Xenazine 25 mg tablete	FI/H/0810/001	H/14/01677/001	BAUSCH HEALTH IRELAND LIMITED	SI
Xenazine 25 mg tabletit	FI/H/0810/001	31115	BAUSCH HEALTH IRELAND LIMITED	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