



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 May 2016
EMA/423939/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: tetrabenazine

Procedure no.: PSUSA/00002911/201510



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		58924.00.00	Temmler Pharma Gmbh	Germany
Nitoman		70142	Pharmaswiss česká Republika S.R.O.	Spain
Nitoman		PA 1703/1/1	Lundbeck Uk Llp	Ireland
Xenazina		036688012	Chiesi Farmaceutici S.P.A.	Italy
Xenazine		19824	Medilink A/S	Sweden
Xenazine		3400936931916	Eusa Pharma Sas	France
Xenazine		PL 39386/0001	Lundbeck Uk Llp	United Kingdom
Xenazine	FI/H/0810/001	14-0062	Pharmaswiss česká Republika S.R.O.	Latvia
Xenazine	FI/H/0810/001	22228	Pharmaswiss česká Republika S.R.O.	Poland
Xenazine	FI/H/0810/001	31115	Pharmaswiss česká Republika S.R.O.	Finland

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	FI/H/0810/001	49649/13.06.2014	Pharmaswiss česká Republika S.R.O.	Greece
Xenazine	FI/H/0810/001	77/0104/14-S	Pharmaswiss česká Republika S.R.O.	Slovakia
Xenazine	FI/H/0810/001	7851/2015/01	Pharmaswiss česká Republika S.R.O.	Romania
Xenazine	FI/H/0810/001	H/14/01677/001	Pharmaswiss česká Republika S.R.O.	Slovenia
Xenazine	FI/H/0810/001	LT/1/14/3513/001	Pharmaswiss česká Republika S.R.O.	Lithuania
Xenazine	FI/H/0810/001	OGYI-T-22625/01	Pharmaswiss česká Republika S.R.O.	Hungary