



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2017
EMA/50914/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Bismuth subcitrate potassium / metronidazole /
tetracycline

Procedure no.: PSUSA/00010199/201605



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
Pylera 140 mg/125 mg/125 mg kemény kapszula	DE/H/2467/001	OGYI-T-22666/01	APTALIS PHARMA SAS	HU
Pylera 140 mg/125 mg/125 mg tvrdé kapsuly	DE/H/2467/001	15/0199/14-S	APTALIS PHARMA SAS	SK
Пилера 140 mg/125 mg/125 mg твърди капсули	DE/H/2467/001	20140372	APTALIS PHARMA SAS	BG
Pylera 140 mg/125 mg/125 mg καψάκια	DE/H/2467/001	2696	APTALIS PHARMA SAS	GR
Pylera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	78257.00.00	APTALIS PHARMA SAS	DE

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
Pylera 140 mg/125 mg/125 mg, gélule	DE/H/2467/001	34009 218 042 01	APTALIS PHARMA SAS	FR
Tryplera 140 mg/125 mg/125 mg, gélules	DE/H/2467/001	BE405666	APTALIS PHARMA SAS	BE
Tryplera 140 mg/125 mg/125 mg capsules	DE/H/2467/001	BE405666	APTALIS PHARMA SAS	BE
Tryplera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	BE405666	APTALIS PHARMA SAS	BE
Pylera 140 mg +125 mg + 125 mg kapsułki, twarde	DE/H/2467/001	19518	APTALIS PHARMA SAS	PL

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
PYLERA 140 mg/125 mg/125 mg, cápsulas	DE/H/2467/001	75095	APTALIS PHARMA SAS	ES
Pylera 140 mg + 125 mg + 125 mg cápsulas	DE/H/2467/001	5398243	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	PT
Pylera 140 mg/125 mg/125 mg capsules	DE/H/2467/001	PA1637/001/001	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	IE
Pylera 140 mg/125 mg/125 mg capsules	DE/H/2467/001	PL 45496/0008	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	UK
Pylera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	135697	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	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
Pylera 140 mg/125 mg/125 mg capsule	DE/H/2467/001	041527019	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	IT
Pylera 140 mg/125 mg/125 mg tvrdé tobolky	DE/H/2467/001	09/248/14-C	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	CZ