



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/270645/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: Bismuth subcitrate potassium / metronidazole /
tetracycline

Procedure no.: PSUSA/00010199/201505



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	DE/H/2467/001	041527019	Aptalis Pharma Sas	Italy
Pylera	DE/H/2467/001	09/248/14-C	Aptalis Pharma Sas	Czech Republic
Pylera	DE/H/2467/001	15/0199/14-S	Aptalis Pharma Sas	Slovakia
Pylera	DE/H/2467/001	19518	Aptalis Pharma Sas	Poland
Pylera	DE/H/2467/001	34009 218 042 01	Aptalis Pharma Sas	France
Pylera	DE/H/2467/001	75095	Aptalis Pharma Sas	Spain
Pylera	DE/H/2467/001	78257.00.00	Aptalis Pharma Sas	Germany
Pylera	DE/H/2467/001	OGYI-T-22666/01	Aptalis Pharma Sas	Hungary
Pylera	DE/H/2467/001	PA1637/001/001	Aptalis Pharma Sas	Ireland
Pylera	DE/H/2467/001	PL 32507/0001	Aptalis Pharma Sas	United Kingdom
Pylera	DE/H/2467/001/E/001	135697	Aptalis Pharma Sas	Austria
Pylera	DE/H/2467/001/E/001	2696	Aptalis Pharma Sas	Greece
Tryplera	DE/H/2467/001	BE405666	Aptalis Pharma Sas	Belgium
пилера	DE/H/2467/001/E/001	20140372	Aptalis Pharma Sas	Bulgaria
Pylera	DE/H/2467/001		Aptalis Pharma Sas	Portugal