



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/54617/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bismuth subcitrate potassium / metronidazole / tetracycline

Procedure No. PSUSA/00010199/202405



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 0 1	LABORATOIRES JUVISE PHARMACEUTICALS	FR
Tryplera 140 mg/125 mg/125 mg, gélules.	DE/H/2467/001	BE405666	LABORATOIRES JUVISE PHARMACEUTICALS	BE
Tryplera 140 mg/125 mg/125 mg capsules.	DE/H/2467/001	BE405666	LABORATOIRES JUVISE PHARMACEUTICALS	BE
Tryplera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	BE405666	LABORATOIRES JUVISE PHARMACEUTICALS	BE
Pylera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	78257.00.00	LABORATOIRES JUVISE PHARMACEUTICALS	DE
Pylera 140 mg/125 mg/125 mg Hartkapseln	DE/H/2467/001	135697	LABORATOIRES JUVISE PHARMACEUTICALS	AT
Pylera 140 mg/125 mg/125 mg tvrdé tobolky	DE/H/2467/001	09/248/14-C	LABORATOIRES JUVISE PHARMACEUTICALS	CZ
Pylera 140 mg/125 mg/125 mg tvrdé kapsuly	DE/H/2467/001	15/0199/14-S	LABORATOIRES JUVISE PHARMACEUTICALS	SK
Pylera 140 mg +125 mg + 125 mg kapsułki, twarde	DE/H/2467/001	19518	LABORATOIRES JUVISE PHARMACEUTICALS	PL
PYLERA 140 mg/125 mg/125 mg, cápsulas.	DE/H/2467/001	75095	LABORATOIRES JUVISE PHARMACEUTICALS	ES
Pylera 140 mg + 125 mg + 125 mg cápsulas.	DE/H/2467/001	5398243	LABORATOIRES JUVISE PHARMACEUTICALS	PT

Pylera 140 mg/125 mg/125 mg capsule	DE/H/2467/001	041527019	LABORATOIRES JUVISE PHARMACEUTICALS	IT
Pylera 140 mg/125 mg/125 mg capsules	not available	PL 43311/0001	LABORATOIRES JUVISE PHARMACEUTICALS	XI