



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 July 2023
EMA/112269/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bacillus clausii multi-antibioresistant spores

Procedure No. PSUSA/00000284/202211



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
Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió	not available	OGYI-T-10357/08	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió	not available	OGYI-T-10357/06	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
Normaflore Extra 4 milliárd/5 ml belsőleges szuszpenzió	not available	OGYI-T-10357/07	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
Normaflore belsőleges szuszpenzió	not available	OGYI-T-10357/05	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
Normaflore belsőleges szuszpenzió	not available	OGYI-T-10357/01	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
Normaflore belsőleges szuszpenzió	not available	OGYI-T-10357/02	OPELLA HEALTHCARE COMMERCIAL KFT.	HU
ENTEROGERMINA 6 miliardi/2 g polvere per sospensione orale	not available	013046091	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 6 miliardi/2 g polvere per sospensione orale	not available	013046103	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 2 miliardi capsule rigide	not available	013046053	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 2 miliardi capsule rigide	not available	013046065	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 2 miliardi / 5 ml sospensione orale	not available	013046040	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 2 miliardi / 5 ml sospensione orale	not available	013046038	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 4 miliardi / 5 ml sospensione orale	not available	013046077	OPELLA HEALTHCARE ITALY S.R.L.	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
ENTEROGERMINA 4 miliardi / 5 ml sospensione orale	not available	013046089	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 6 miliardi/2 g polvere orale	not available	013046139	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 6 miliardi/2 g polvere orale	not available	013046115	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 6 miliardi/2 g polvere orale	not available	013046141	OPELLA HEALTHCARE ITALY S.R.L.	IT
ENTEROGERMINA 6 miliardi/2 g polvere orale	not available	013046127	OPELLA HEALTHCARE ITALY S.R.L.	IT