



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 December 2015
EMA/382258/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: promestriene (cream and vaginal capsules)

Procedure no.: PSUSA/00009271/201503



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
Colpotrophine		026613048	Ratiopharm Italia S.R.L.	Italy
Colpotrophine		026613051	Ratiopharm Italia S.R.L.	Italy
Colpotrophine		3655/2011/01	Laboratoire Theramex S.A.M	Romania
Colpotrophine		4152/2011/01	Laboratoire Theramex S.A.M	Romania
Colpotrophine		8626309	Laboratoire Theramex S.A.M	Portugal
Colpotrophine		8626408	Laboratoire Theramex S.A.M	Portugal
Colpotrophine		NL 10315	Laboratoire Theramex S.A.M	France
Colpotrophine		NL 9771	Laboratoire Theramex S.A.M	France
Colpotrophine vaginal soft capsule		MA 017/00201	Laboratoire Theramex S.A.M	Malta
Colpotrophine		MA 017/00202	Laboratoire Theramex S.A.M	Malta