



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2018
EMA/785057/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: promestriene (cream and vaginal capsules)

Procedure no.: PSUSA-00009271-201803



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
COLPOTROFIN 10 mg/g crema vaginal	not available	55.594	TEVA PHARMA S.L.U.	ES
COLPOTROPHINE	not available	026613051	RATIOPHARM ITALIA S.R.L.	IT
COLPOTROPHINE	not available	026613048	RATIOPHARM ITALIA S.R.L.	IT
COLPOTROPHINE 1 POUR CENT, crème	not available	NL 10315	TEVA SANTÉ	FR
Colpotrophine 10 mg Cápsulas moles vaginais	not available	8626309	LABORATOIRE THERAMEX S.A.M.	PT
COLPOTROPHINE, 1% Creme vaginal	not available	8626408	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
COLPOTROPHINE, capsule vaginale	not available	NL 9771	LABORATOIRE THERAMEX S.A.M.	FR