



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/751259/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: promestriene (cream and vaginal capsules)

Procedure No.: PSUSA/00009271/201603



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 1 POUR CENT, crème	not available	NL 10315	LABORATOIRE THERAMEX S.A.M.	FR
Colpotrophine 1% crème	not available	NL 10315	LABORATOIRE THERAMEX S.A.M.	FR
COLPOTROPHINE, capsule vaginale	not available	NL 9771	LABORATOIRE THERAMEX S.A.M.	FR
Colpotrophine capsule vaginale	not available	NL 9771	LABORATOIRE THERAMEX S.A.M.	FR
COLPOTROPHINE 10 mg capsule vaginale	not available	3655/2011/01	LABORATOIRE THERAMEX S.A.M.	RO
Colpotrophine vaginal soft capsule	not available	MA 017/00201	LABORATOIRE THERAMEX S.A.M.	MT
COLPOTROPHINE 1 PER CENT, vaginal cream.	not available	MA 017/00202	LABORATOIRE THERAMEX S.A.M.	MT
COLPOTROPHINE	not available	026613051	RATIOPHARM ITALIA S.R.L.	IT
COLPOTROPHINE	not available	026613048	RATIOPHARM ITALIA S.R.L.	IT
Colpotrophine 10 mg capsulas moles vaginais	not available	8626309	LABORATOIRE THERAMEX S.A.M.	PT
COLPOTROPHINE 10 mg/g crema vaginala	not available	4152/2011/01	LABORATOIRE THERAMEX S.A.M.	RO
COLPOTROPHINE, 1% Creme vaginal	not available	8626408	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT