



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2020
EMA/90195/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dienogest / estradiol (HRT indication)

Procedure no.: PSUSA/00010443/201906



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
Climodien 1 mg/2 mg, omhulde tabletten	NL/H/0595/001	RVG 30401	BAYER BV	NL
Climodien 1 mg/2 mg überzogene Tabletten	NL/H/0595/001	63249.00.00	JENAPHARM GMBH & CO KG	DE
Climodien 2 mg + 2 mg comprimidos revestidos	NL/H/0248/001	3644580	BAYER PORTUGAL LDA	PT
Climodien 2 mg + 2 mg comprimidos revestidos	NL/H/0248/001	3644689	BAYER PORTUGAL LDA	PT
Climodien 2 mg/ 2 mg überzogene Tabletten	NL/H/0248/001	2009010072	BAYER SA NV	LU
Climodien 2 mg/2 mg comprimidos recubiertos	NL/H/0248/001	64.051	BAYER HISPANIA SL	ES
Climodien 2 mg/2 mg, omhulde tabletten	NL/H/0248/001	RVG 24830	BAYER BV	NL
Climodien 2/2 mg überzogene Tabletten	NL/H/0248/001	BE227053	BAYER SA NV	BE
Climodien 2/2 mg überzogene Tabletten	NL/H/0248/001	51343.00.00	JENAPHARM GMBH & CO KG	DE

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
Climodien 2/2 mg, comprimés enrobés	NL/H/0248/001	BE227053	BAYER SA NV	BE
Climodien 2/2 mg, omhulde tabletten	NL/H/0248/001	BE227053	BAYER SA NV	BE
Climodien 2mg /2 mg, comprimés enrobés	NL/H/0248/001	2009010072	BAYER SA NV	LU
CLIMODIENE 2 mg/2 mg, comprimé enrobé	NL/H/0248/001	34009 357 624 9 8	BAYER HEALTHCARE	FR
CLIMODIENE 2 mg/2 mg, comprimé enrobé	NL/H/0248/001	34009 357 623 2 0	BAYER HEALTHCARE	FR
KLIMODIEN 2 mg/2 mg obalené tablety	not available	56/204/01-C	BAYER AG	CZ
Lafamme 1 mg/2 mg überzogene Tabletten	NL/H/0652/001	63248.00.00	JENAPHARM GMBH & CO KG	DE
Lafamme 1 mg/2 mg, omhulde tabletten	NL/H/0652/001	RVG 32405	BAYER BV	NL
Lafamme 2 mg/2 mg, omhulde tabletten	NL/H/0249/001	RVG 26285	BAYER BV	NL

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
Lafamme 2/2 mg überzogene Tabletten	NL/H/0249/001	51347.00.00	JENAPHARM GMBH & CO KG	DE