



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2018
EMA/782577/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dienogest / ethinylestradiol

Procedure no.: PSUSA/00001057/201803



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
Celimona®	DE/H/0327/001	38619.00.00	JENAPHARM GMBH & CO KG	DE
Valette, 2 mg + 0,030 mg, comprimidos revestidos	DE/H/0327/001	4037388	BAYER PORTUGAL LDA	PT
Valette-Dragees	DE/H/0327/001	1-24452	BAYER AUSTRIA GMBH	AT
Valette, 2 mg + 0,030 mg, comprimidos revestidos	DE/H/0327/001	4037487	BAYER PORTUGAL LDA	PT
Celimone®	DE/H/0331/001	51732.00.00	BAYER PHARMA AG	DE
Jeanine 2 mg/ 0,03 mg obalené tablety	not available	17/407/00-C	BAYER AG	CZ
Жанин 0,030 mg/ 2,0 mg обвити таблетки	not available	20010627	BAYER AG	BG
Jeanine, 2000/30 mikrogrammi kaetud tabletid	not available	380002	BAYER AG	EE
Maxim®	not available	53560.00.00	JENAPHARM GMBH & CO KG	DE
Jeanine 2000/30 mikrogramų dengtos tabletės	not available	LT/1/01/2565/001	BAYER AG	LT
Jeanine, 0,03 mg + 2 mg, tabletki powlekane	not available	10180	BAYER AG	PL
Jeanine 2000/30 mikrogramu apvalkotās tabletes	not available	02-0097	BAYER AG	LV
Valette®	not available	3001416.00.00	JENAPHARM GMBH & CO KG	DE

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Jeanine 2 mg/0,03 mg obalené tablety	not available	17/0034/01-S	BAYER PHARMA AG	SK
Foxinette 0,03 mg/2 mg 21+7 - Filmdabletten	DE/H/4577/001	137513	SANDOZ GMBH	AT
Cemisiana	DE/H/4577/001	044581027	SANDOZ S.P.A.	IT
Cemisiana	DE/H/4577/001	044581039	SANDOZ S.P.A.	IT
Cemisiana	DE/H/4577/001	044581041	SANDOZ S.P.A.	IT
Cemisiana	DE/H/4577/001	004581015	SANDOZ S.P.A.	IT
Etinilestradiol/dienogest Sandoz 0,03 mg/2mg filmsko obložene tablete	DE/H/4577/001	H/17/02336/001	SANDOZ PHARMACEUTICALS D.D.	SI
Etinilestradiol/dienogest Sandoz 0,03 mg/2mg filmsko obložene tablete	DE/H/4577/001	H/17/02336/003	SANDOZ PHARMACEUTICALS D.D.	SI
Etinilestradiol/dienogest Sandoz 0,03 mg/2mg filmsko obložene tablete	DE/H/4577/001	H/17/02336/002	SANDOZ PHARMACEUTICALS D.D.	SI
Etinilestradiol/dienogest Sandoz 0,03 mg/2mg filmsko obložene tablete	DE/H/4577/001	H/17/02336/004	SANDOZ PHARMACEUTICALS D.D.	SI
Mistra 2 mg/0,03 mg filmom obložene tablete	DE/H/3938/001	HR-H-406840363	GEDEON RICHTER PLC.	HR
Dienogest ed etinilestradiolo Gedeon Richter 2 mg/0,03 mg compresse rivestite con film	DE/H/3938/001	042930014	GEDEON RICHTER PLC.	IT

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Dienogest ed etinilestradiolo Gedeon Richter 2 mg/0,03 mg compresse rivestite con film	DE/H/3938/001	042930026	GEDEON RICHTER PLC.	IT
Dienogest ed etinilestradiolo Gedeon Richter 2 mg/0,03 mg compresse rivestite con film	DE/H/3938/001	042930038	GEDEON RICHTER PLC.	IT
Dienogest/Ethinylestradiol Richter 21+7 2 mg/0,03 mg Filmtabletten	DE/H/3938/001	90678.00.00	GEDEON RICHTER PLC.	DE
Sibilla 0,03 mg/2 mg 21 + 7 Filmtabletten	DE/H/3938/001	136815	GEDEON RICHTER PLC.	AT
Sibilla 21+7 2 mg/0,03 mg Filmtabletten	DE/H/3691/001	88410.00.00	GEDEON RICHTER PLC.	DE