



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2023
EMA/134265/2024
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): dienogest / ethinylestradiol

Procedure no.: PSUSA/00001057/202303



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
Ardiena 2 mg/0,03 mg potahované tablety	not available	17/791/16-C	ARDEZ PHARMA	CZ
Dienorette 2 mg/0,03 mg filmdragerade tabletter	FI/H/1161/001	55196	EXELTIS HEALTHCARE S.L	SE
Dienorette 2 mg/0,03 mg kalvopäällysteinen tabletti	FI/H/1161/001	34447	EXELTIS HEALTHCARE S.L	FI
Jeanine, 0,03 mg + 2 mg, tabletki powlekane	not available	10180	BAYER AG	PL
Jeanine, 2000/30 mikrogrammi kaetud tabletid	not available	380002	BAYER AG	EE
Celimone®	DE/H/0331/001	51732.00.00	JENAPHARM GMBH & CO KG	DE
Cemisiana	DE/H/4577/001	044581027	SANDOZ S.P.A.	IT
Cemisiana 0,03 mg/2 mg compresse rivestite con film.	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	044581015	SANDOZ S.P.A.	IT
Sibilla 21+7 2 mg/0,03 mg Filmtabletten	DE/H/3691/001	88410.00.00	GEDEON RICHTER PLC.	DE
Maxim®	not available	53560.00.00	JENAPHARM GMBH & CO KG	DE
Жанин 0,030 mg/ 2,0 mg обвити таблетки	not available	20010627	BAYER AG	BG
Valette®	not available	3001416.00.00	JENAPHARM GMBH & CO KG	DE
Sibillette 2 mg/0,03 mg compresse rivestite con film	DE/H/3938/001	042930014	GEDEON RICHTER PLC.	IT
Sibillette 2 mg/0,03 mg compresse rivestite con film	DE/H/3938/001	042930026	GEDEON RICHTER PLC.	IT
Sibillette 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
Jeanine 2 mg/0,03 mg obalené tablety	not available	17/0034/01-S	BAYER AG	SK
Jeanine 2000/30 mikrogramų dengtos tabletės	not available	LT/1/01/2565/001	BAYER AG	LT
Jeanine 2000/30 mikrogramu	not available	02-0097	BAYER AG	LV

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apvalkotās tabletes				
Jeanine 2 mg/ 0,03 mg obalené tablety	not available	17/407/00-C	BAYER AG	CZ
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