



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2019
EMA/278136/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dienogest / estradiol (contraception indication)

Procedure no.: PSUSA/00010444/201809



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
Qlaira comprimidos recubiertos con película	NL/H/1230/001	70.367	BAYER HISPANIA SL	ES
Qlaira, comprimé pelliculé	NL/H/1230/001	BE327792	BAYER SA NV	BE
Qlaira, Filmtabletten	NL/H/1230/001	BE327792	BAYER SA NV	BE
Qlaira filmom obložene tablete	NL/H/1230/001	HR-H-182628999-01	BAYER DOO	HR
Qlaira filmom obložene tablete	NL/H/1230/001	HR-H-182628999-02	BAYER DOO	HR
Qlaira filmom obložene tablete	NL/H/1230/001	HR-H-182628999-03	BAYER DOO	HR
Qlaira filmtabletta	NL/H/1230/001	OGYI-T-20898/02	BAYER AG	HU
Qlaira filmtabletta	NL/H/1230/001	OGYI-T-20898/03	BAYER AG	HU
Qlaira, Filmtabletten	NL/H/1230/001	2009080009	BAYER SA NV	LU
Qlaira® filmdragerade tabletter	NL/H/1230/001	24337	BAYER OY	FI
Qlaira filmsko obložene tablete	NL/H/1230/001	H/08/01308/001	BAYER D.O.O	SI
Qlaira filmsko obložene tablete	NL/H/1230/001	H/08/01308/003	BAYER D.O.O	SI
Qlaira filmsko obložene tablete	NL/H/1230/001	H/08/01308/002	BAYER D.O.O	SI
Qlaira, filmdrasjerte tabletter	NL/H/1230/001	07-5434	BAYER AB	NO
Qlaira, potahované tablety	NL/H/1230/001	17/032/09-C	BAYER AG	CZ
Qlaira plėvele dengtos tabletės	VNL/H/1230/001	LT/1/09/1512/002	BAYER AG	LT
Qlaira, comprimidos revestidos por película	NL/H/1230/001	5170071	BAYER PORTUGAL LDA	PT
Qlaira Filmtabletten	NL/H/1230/001	1-28003	BAYER AUSTRIA GMBH	AT
Qlaira, filmomhulde	NL/H/1230/001	BE327792	BAYER SA NV	BE

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tabletten				
Klaira, compresse rivestite con film	NL/H/1230/001	038900039	BAYER SPA	IT
Qlaira plévele dengtos tabletės	VNL/H/1230/001	LT/1/09/1512/001	BAYER AG	LT
Qlaira plévele dengtos tabletės	VNL/H/1230/001	LT/1/09/1512/003	BAYER AG	LT
Klaira, compresse rivestite con film	NL/H/1230/001	038900027	BAYER SPA	IT
Klaira, compresse rivestite con film	NL/H/1230/001	038900015	BAYER SPA	IT
Qlaira, comprimés pelliculés	NL/H/1230/001	2009080009	BAYER SA NV	LU
Qlaira, comprimidos revestidos por película	NL/H/1230/001	5170063	BAYER PORTUGAL LDA	PT
Qlaira film-coated tablets	NL/H/1230/001	PA1410/058/001	BAYER LTD	IE
Qlaira, filmdragerade tabletter	NL/H/1230/001	26328	BAYER AB	SE
QLAIRA, comprimé pelliculé	NL/H/1230/001	34009 390 949 0 8	BAYER HEALTHCARE	FR
QLAIRA, comprimé pelliculé	NL/H/1230/001	34009 390 948 4 7	BAYER HEALTHCARE	FR
QLAIRA, comprimé pelliculé	NL/H/1230/001	34009 390 950 9 7	BAYER HEALTHCARE	FR
Qlaira filmomhulde tabletten	NL/H/1230/001	RVG 101491	BAYER BV	NL
Qlaira, film-coated tablets	NL/H/1230/001	MA513/01401	BAYER PLC	MT
Qlaira, filmovertrukne tabletter	NL/H/1230/001	42468	BAYER AB	DK
Qlaira, επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/1230/001	8160/13/10-3-2014	BAYER HELLAS SA	GR
Qlaira, επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/1230/001	20525	BAYER HELLAS SA	CY

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Qlaira filmtabletta	NL/H/1230/001	OGYI-T-20898/01	BAYER AG	HU
Qlaira kalvopäällysteiset tabletit	NL/H/1230/001	24337	BAYER OY	FI
Qlaira, õhukese polümeerikattega tabletid	NL/H/1230/001	614308	BAYER AG	EE
Qlaira filmuhúðaðar töflur	NL/H/1230/001	IS/1/08/028/01	BAYER AB	IS
Qlaira Filmtabletten Estradiolvalerat/Dienogest	NL/H/1230/001	71897.00.00	JENAPHARM GMBH & CO KG	DE
Qlaira, film-coated tablets	NL/H/1230/001	PL00010/0576	BAYER PLC	UK
Qlaira filmom obalené tablety	NL/H/1230/001	17/0590/08-S	BAYER SPOL SRO	SK
Qlaira apvalkotās tabletes	NL/H/1230/001	08-0347	BAYER AG	LV
Qlaira, tabletki powlekane	NL/H/1230/001	15221	BAYER AG	PL
Qlaira comprimate filmate	NL/H/1230/001	6582/2014/01	BAYER AG	RO
Qlaira comprimate filmate	NL/H/1230/001	6582/2014/02	BAYER AG	RO
Qlaira comprimate filmate	NL/H/1230/001	6582/2014/-03	BAYER AG	RO