



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/167446/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dienogest / estradiol (contraception indication)

Procedure no.: PSUSA/00010444/202309

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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, comprimés pelliculés	NL/H/1230/001	BE327792	BAYER SA NV	BE
Qlaira, Filmtabletten	NL/H/1230/001	BE327792	BAYER SA NV	BE
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

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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	NL/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 tabletten	NL/H/1230/001	BE327792	BAYER SA NV	BE
Klaira, compresse rivestite con film	NL/H/1230/001	038900039	BAYER SPA	IT
Qlaira plėvele dengtos tabletės	NL/H/1230/001	LT/1/09/1512/001	BAYER AG	LT

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Qlaira plèvele dengtos tabletès	NL/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

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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 B.V.	NL
Qlaira, filmovertrukne tabletter	NL/H/1230/001	42468	BAYER AB	DK
Qlaira, επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/1230/001	8160/13/10-03-2014	BAYER HELLAS SA	GR
Qlaira, επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/1230/001	20525	BAYER HELLAS SA	CY
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

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Qlaira Filmtabletten Estradiolvalerat/Dienogest	NL/H/1230/001	71897.00.00	JENAPHARM GMBH & CO KG	DE
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
Qlaira film-coated tablets	NL/H/1230/001	MA639/02701	BAYER LTD	MT
Qlaira filmom obložene tablete	NL/H/1230/001	HR-H-182628999	BAYER DOO	HR

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Qlaira, film-coated tablets	NL/H/1230/001	PL00010/0576	BAYER PLC	XI