



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/589993/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: levonorgestrel

Procedure No.: PSUSA/00001856/201412



Product Name (in authorisation country)	MRP / DCP Authorisation Number	National Authorisation Number	MAH of product in the member state	Member state where the product is authorised
28 Mini		3000361.00.00	Jenapharm Gmbh & Co Kg	DE
Donasert	UK/H/3030/001	5672/2013/01	Gedeon Richter România S.A.	RO
Emergency Contraceptive	UK/H/4569/001/DC	PL 04854/0105	Gedeon Richter Plc.	GB
Escapelle	NOT APPLICABLE	UP/I-530-09/07-01/195	Sandoz D.O.O.	HR
Escapelle	NULL	04-0318	Gedeon Richter Plc.	LV
Escapelle	NULL	17/0187/04-S	Gedeon Richter Plc.	SK
Escapelle	NULL	20060032	Gedeon Richter Plc.	BG
Escapelle	NULL	443104	Gedeon Richter Plc.	EE
Escapelle	NULL	5363-I-113/14	Gedeon Richter Plc.	SI
Escapelle	NULL	6983/2006/01	Gedeon Richter Plc.	RO
Escapelle	NULL	OGYI-T-9330/01	Gedeon Richter Plc.	HU
Escapelle	UK/H/0803/001/MR	12048	Gedeon Richter Plc.	PL
Escapelle	UK/H/0803/001/MR	17/168/07-C	Gedeon Richter Plc.	CZ
Escapelle	UK/H/0803/001/MR	LT/1/06/0511/001	Gedeon Richter Plc.	LT
Fleree	SE/H/1186/01/DC	13-0048	Bayer Pharma Ag	LV
Fleree	SE/H/1186/01/DC	805513	Bayer Pharma Ag	EE
Fleree	SE/H/1186/01/DC	LT/1/13/3219/001	Bayer Pharma Ag	LT
Fleree	SE/H/1186/01/DC	LT/1/13/3219/002	Bayer Pharma Ag	LT
Isteranda	NL/H/2656/001	12-9045	Sandoz A/S	NO
Jadelle	FI/H/128/01	12512	Bayer Oy	FI
Jadelle	FI/H/128/01	5161781	Bayer Oy	PT
Jaydess		1-31748	Bayer Austria Gmbh	AT
Jaydess	SE/H/1186/01/DC	042522019	Bayer Spa	IT
Jaydess	SE/H/1186/01/DC	042522021	Bayer Spa	IT
Jaydess	SE/H/1186/01/DC	1-31748	Bayer Austria Gmbh	AT
Jaydess	SE/H/1186/01/DC	11-8775	Bayer Ab	NO

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Jaydess	SE/H/1186/01/DC	17/0024/13-S	Bayer Spol Sro	SK
Jaydess	SE/H/1186/01/DC	2013040105	Bayer Sa Nv	LU
Jaydess	SE/H/1186/01/DC	21101	Bayer Pharma Ag	PL
Jaydess	SE/H/1186/01/DC	30387	Bayer Oy	FI
Jaydess	SE/H/1186/01/DC	47317	Bayer Ab	SE
Jaydess	SE/H/1186/01/DC	49987	Bayer Ab	DK
Jaydess	SE/H/1186/01/DC	5363-I-683/13	Bayer D.O.O	SI
Jaydess	SE/H/1186/01/DC	5566617	Berlex Especialidades Farmaceuticas Lda	PT
Jaydess	SE/H/1186/01/DC	5566625	Berlex Especialidades Farmaceuticas Lda	PT
Jaydess	SE/H/1186/01/DC	5638/2013/01-02	Bayer Pharma Ag	RO
Jaydess	SE/H/1186/01/DC	77.169	Bayer Hispania Sl	ES
Jaydess	SE/H/1186/01/DC	86537.00.00	Jenapharm Gmbh & Co Kg	DE
Jaydess	SE/H/1186/01/DC	BE433544	Bayer Sa Nv	BE
Jaydess	SE/H/1186/01/DC	IS/1/13/001/01	Bayer Ab	IS
Jaydess	SE/H/1186/01/DC	MA 513/05301	Bayer Plc	MT
Jaydess	SE/H/1186/01/DC	NL 41969 (CIP: 340009 274 194 7 8)	Bayer Healthcare	FR
Jaydess	SE/H/1186/01/DC	NL 41969 (CIP: 340009 585 070 8 3)	Bayer Healthcare	FR
Jaydess	SE/H/1186/01/DC	OGYI-T-22404/01	Bayer Hungaria Kft	HU
Jaydess	SE/H/1186/01/DC	PA 1410/68/001	Bayer Ltd	IE
Jaydess	SE/H/1186/01/DC	PL 00010/0587	Bayer Plc	GB
Jaydess	SE/H/1186/01/DC	RVG 111192	Bayer Bv	NL
Jaydess	SE/H/1186/001/DC	17/049/13-C	Bayer Pharma Ag	CZ
Jaydess	SE/H/1186/01/DC	PL 00010/0587	Bayer Plc	GB
Levonelle	UK/H/0803/001/MR	PA 0818/004/002	Medimpex Uk Ltd.	IE
Levonelle	UK/H/0803/001/MR	PL 05276/0019	Medimpex Uk Ltd.	GB
Levonelle One Step	NULL	PL 05276/0020	Medimpex Uk Ltd.	GB
Levonelle-2tm	UK/H/0363/001/MR	PL05276/0016	Medimpex Uk Ltd.	GB

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Levonorgestrel Biogaran	UK/H/0803/001/MR	373 075-6	Medimpex Uk Ltd.	FR
Levosert	UK/H/5491/001	BE446586	Mithra Pharmaceuticals Sa	BE
Levosert	UK/H/3030/001/DC	13-0032	Gedeon Richter Plc.	LV
Levosert	UK/H/3030/001/DC	17/0236/13-S	Gedeon Richter Plc.	SK
Levosert	UK/H/5491/001/DC	2014060143	Mithra Pharmaceuticals	LU
Levosert	UK/H/3030/001/DC	20130077	Gedeon Richter Plc.	BG
Levosert	UK/H/3030/001/DC	21336	Gedeon Richter Polska Sp. Z. O.O.	PL
Levosert	UK/H/3030/001/DC	LT/1/13/3319/001	Gedeon Richter Plc.	LT
Levosert	UK/H/3030/001/DC	OGYI-T-22505/01	Gedeon Richter Plc.	HU
Levosert 20 micrograms/24 hours Intrauterine Delivery System	MA628/12001		Actavis Group PTC	MT
Lonel	UK/H/0803/001/MR	038802017/M	Medimpex Uk Ltd.	IT
Luadei	SE/H/1187/01/DC	1-31749	Bayer Austria Gmbh	AT
Luadei	SE/H/1187/01/DC	47573	Bayer Ab	SE
Luadei	SE/H/1187/01/DC	77.170	Bayer Hispania SI	ES
Luadei	SE/H/1187/01/DC	86538.00.00	Jenapharm Gmbh & Co Kg	DE
Luadei	SE/H/1187/01/DC	RVG 111378	Bayer Bv	NL
LUADEI		NL 41970 (CIP: 340009 585 071 4 4)	Bayer HealthCare France	FR
LUADEI		NL 41969 (CIP: 340009 274 195 3 9)	Bayer HealthCare France	FR
Luadei	SE/H/1187/01/DC	PL 00010/0588	Bayer Plc	GB
Microlut		6929492.00.00	Jenapharm Gmbh & Co Kg	DE
Microlut	not applicable	BE083115	Bayer SA NV, Belgium	BE
Microlut	not applicable	1983070100	Bayer SA NV, Belgium	LU
Microluton		6424	Bayer Oy	FI
Microval	not applicable	NL 11033	Pfizer Holding France	FR
Microval 30 Microgram Tablets	not applicable	PA 822/067/001	Pfizer Healthcare Ireland	IR
MIREFFIK	UK/H/5666/01/DC	BE463626	EFFIK Benelux	BE

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Mireffik	UK/H/5666/001/DC	PL 34096/0008	Mithra Pharmaceuticals	UK
Mirena		018612	Bayer Hellas Sa	CY
Mirena		10212	Bayer Oy	FI
Mirena		11668	Bayer Oy	SE
Mirena		127696	Bayer Pharma Ag	EE
Mirena		14881	Bayer Oy	DK
Mirena		2011051166	Bayer Sa Nv	LU
Mirena		30495.00.00	Jenapharm Gmbh & Co Kg	DE
Mirena		41880.00.00	Jenapharm Gmbh & Co Kg	DE
Mirena		5363-I-2248/11	Bayer Oy	SI
Mirena		PL 00010/0547	Bayer Plc	GB
Mirena		RVG 16681	Bayer Bv	NL
Mirena		UP/I-530-09/10-02/42	Bayer Doo	HR
Mirena	PT/H/100/01	11959	Bayer Pharma Ag	PL
Mirena	PT/H/100/01	2477784	Bayer Oy	PT
Mirena	PT/H/100/01	63.158	Bayer Hispania Sl	ES
MIRENA	not applicable	20731/1-4-2008	Bayer Hellas SA, Greece	EL
Mirena	not applicable	920074 (IS)	Bayer Oy, Finland	IS
Mirena	not applicable	PA 1410/8/1	Bayer Ltd, Ireland	IR
Mirena	not applicable	029326016	Bayer Oy, Finland	IT
Mirena	not applicable	99-0502	Bayer Oy, Finland	LV
Mirena	not applicable	LT/1/98/0172/001	Bayer Oy, Finland	LT
Mirena	not applicable	7935	Bayer Oy, Finland	NO
Mirena	not applicable	7884/2006/01	Bayer Oy, Finland	RO
Mirena	not applicable	17/0234/99-S	Bayer Oy, Finland	SK
Mirena	not applicable	1-21529	Bayer Austria Gmbh	AT
MIRENA	not applicable	DIU 0012 (CIP: 34009 339 292 8 2)	Bayer Healthcare	FR
Mirena		17/372/97-C	Bayer Oy	CZ

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Mirena méhen belüli gyógyszerleadó rendszer	National procedure	OGYI-T-6210/01	Bayer Pharma AG	HU
Mirena®	not applicable	MA513/03901	Bayer Plc	MT
Mirene	not applicable	BE170737	Bayer SA NV, Belgium	BE
Norgeston		PL 00010/0550	Bayer Plc	GB
Norgeston		PL 00010/0550	Bayer Plc	GB
Norlevo		019380	Laboratoire Hra Pharma	CY
Norlevo		05-3426	Laboratoire Hra Pharma	NO
Norlevo		20222	Laboratoire Hra Pharma	CY
Norlevo		1999-7321	Laboratoire Hra Pharma	NO
Norlevo	FR/H/146/01	0280209	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/01	034884015	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/01	034884027	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/01	034884039	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/01	034884041	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/01	034884054	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/01	15119	Laboratoire Hra Pharma	FI
Norlevo	FR/H/146/01	32052	Laboratoire Hra Pharma	DK
Norlevo	FR/H/146/01	34009 349 575 2 9	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/01	34009 561 339 7 0	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/01	34009 561 340 5 2	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/01	34009 561 341 1 3	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/01	34009 561 342 8 1	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/01	59052/20-12-2012	Laboratoire Hra Pharma	GR
Norlevo	FR/H/146/01	BE214523	Laboratoire Hra Pharma	BE
Norlevo	FR/H/146/01	IS/1/04/022/01	Laboratoire Hra Pharma	IS
Norlevo	FR/H/146/01	PA/1166/1/1	Laboratoire Hra Pharma	IE
Norlevo	FR/H/146/01	RVG 24996	Laboratoire Hra Pharma	NL

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Norlevo	FR/H/146/02	034884066	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/02	034884078	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/02	034884080	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/02	034884092	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/02	034884104	Laboratoire Hra Pharma	IT
Norlevo	FR/H/146/02	0409736	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/02	0409753	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/02	0409767	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/02	0409771	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/02	0409784	Laboratoire Hra Pharma	LU
Norlevo	FR/H/146/02	20803	Laboratoire Hra Pharma	FI
Norlevo	FR/H/146/02	22234	Laboratoire Hra Pharma	SE
Norlevo	FR/H/146/02	34009 364 137 2 6	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/02	34009 565 510 2 6	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/02	34009 565 511 9 4	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/02	34009 565 512 5 5	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/02	34009 565 513 1 6	Laboratoire Hra Pharma	FR
Norlevo	FR/H/146/02	37788	Laboratoire Hra Pharma	DK
Norlevo	FR/H/146/02	5363-I-1946/12	Laboratoire Hra Pharma	SI
Norlevo	FR/H/146/02	74875/20-12-2012	Laboratoire Hra Pharma	GR
Norlevo	FR/H/146/02	BE 277356	Laboratoire Hra Pharma	BE
Norlevo	FR/H/146/02	BE277356	Laboratoire Hra Pharma	BE
Norlevo	FR/H/146/02	IS/1/05/018/01	Laboratoire Hra Pharma	IS
Norlevo	FR/H/146/02	PA 1166/2/1	Laboratoire Hra Pharma	IE
Norlevo	FR/H/146/02	RVG 32303	Laboratoire Hra Pharma	NL
PiDaNa		75074.00.00	Laboratoire HRA Pharma	DE
Postinor	UK/H/0803/001/IB/009	05-3275	Medimpex Uk Ltd.	NO
Postinor	UK/H/0363/001/MR	2001040001	Medimpex Uk Ltd.	LU

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Postinor		UK/H/0363/001/MR	BE275186	Medimpex Uk Ltd.
Postinor	UK/H/0803/001	39843/15-6-2006	Medimpex Uk Ltd.	GR
Postinor	UK/H/0803/001	5693189	Medimpex Uk Ltd.	PT
Postinor	UK/H/0803/001/IA/011	22194	Medimpex Uk Ltd.	SE
Postinor	UK/H/0803/001/IB/009	1-26693	Medimpex Uk Ltd.	AT
Postinor	UK/H/0803/001/IB/009	IS/I/05/016/01	Medimpex Uk Ltd.	IS
Postinor	UK/H/0803/001/IB/009	RVG 32253	Medimpex Uk Ltd.	NL
Postinor	UK/H/0803/001/MR	62588.00.00	Medimpex Uk Ltd.	DE
Postinor -1	UK/H/0803/001/IB/009	67515	Medimpex Uk Ltd.	ES
Postinor-2	NULL	7714/2006/01	Gedeon Richter Plc.	RO
Postinor–2		17/834/99-C	Gedeon Richter Plc.	CZ
Postinor-Duo	NULL	20000358	Gedeon Richter Plc.	BG
Postinor-Duo	NULL	96-0366	Gedeon Richter Plc.	LV
Postinor-Duo	NULL	LT/1/03/3098/001	Gedeon Richter Plc.	LT
Ramonna	UK/H/4569/001/DC	12-0131	Gedeon Richter Plc.	LV
Ramonna	UK/H/4569/001/DC	20088	Gedeon Richter Polska Sp. Z. O.O.	PL
Ramonna	UK/H/4569/001/DC	4737/2012/01	Gedeon Richter România S.A.	RO
Ramonna	UK/H/4569/001/DC	5363-I-1442/12	Gedeon Richter Plc.	SI
Ramonna	UK/H/4569/001/DC	56/0201/12-S	Gedeon Richter Plc.	SK
Ramonna	UK/H/4569/001/DC	781812	Gedeon Richter Plc.	EE
Ramonna	UK/H/4569/001/DC	LT/1/12/2856/001	Gedeon Richter Plc.	LT
Ramonna	UK/H/4569/001/DC	17/126/12-C	Gedeon Richter Plc.	CZ
Ramonna			Gedeon Richter Plc.	BG
Rigesoft	National procedure	OGYI-T-6372/01	Gedeon Richter Plc.	HU
Tableta	UK/H/4569/001/DC	PL 04854/0105	Gedeon Richter Plc.	GB
Tresovelle	UK/H/5491/01/DC	PL 34096/0007	Mithra Pharmaceuticals Sa	GB
Upostelle	NULL	PL04854/0106	Gedeon Richter Plc.	GB
Vikela		34009 358 845 9 6	Laboratoire Hra Pharma	FR

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Vikela		34009 563 889 4 3	Laboratoire Hra Pharma	FR
Vikela		34009 563 890 2 5	Laboratoire Hra Pharma	FR
Vikela		34009 563 891 9 3	Laboratoire Hra Pharma	FR
Vikela		34009 563 892 5 4	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/01	1-23613	Laboratoire Hra Pharma	AT
Vikela	FR/H/146/02	1-26057	Laboratoire Hra Pharma	AT
Vikela	FR/H/146/02	34009 364 138 9 4	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/02	34009 565 514 8 4	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/02	34009 565 515 4 5	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/02	34009 565 516 0 6	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/02	34009 565 517 7 4	Laboratoire Hra Pharma	FR
Vikela	FR/H/146/02	UP/I-530-09/14-01/436	Laboratoire Hra Pharma	HR
джейдас	SE/H/1186/01/DC	20130075	Bayer Pharma Ag	BG
мирена		9800344	Bayer Oy	BG
рамона	UK/H/4569/001/DC	20120195	Gedeon Richter Plc.	BG