



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2022
EMA/152813/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: levonorgestrel (all indications except emergency contraception)

Procedure no.: PSUSA/00010828/202105



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
DONASERT 52 mg (20 microgrammes/24 heures), dispositif intra-utérin	not available	34009 301 487 5 4	GEDEON RICHTER PLC.	FR
Jadelle® 2 x 75 mg implantat	FI/H/0128/001	12512	BAYER OY	FI
Jadelle® 2 x 75 mg - implantaatit	FI/H/0128/001	12512	BAYER OY	FI
JADELLE 2 x 75 mg implante	FI/H/0128/001	5161781	BAYER PORTUGAL LDA	PT
Mirena 20 mikrogramų/24 valandoms vartojimo į gimdos ertmę sistema	not available	LT/1/98/0172/001	BAYER AG	LT
Microlut 30 Mikrogramm überzogene Tabletten	not available	6929492.00.00	JENAPHARM GMBH & CO KG	DE
Mirena 20 mikrogram/24 timmar intrauterint inlägg	not available	11668	BAYER AB	SE
Mirena, IUD 20 microgram/24 uur	not available	RVG 16681	BAYER BV	NL
Mirena 20 mikrogramu/ 24 stundās intrauterīna sistēma	not available	99-0502	BAYER AG	LV
Mirena méhen belüli gyógyszerleadó rendszer	not available	OGYI-T-6210/01	BAYER AG	HU
Jaydess 13,5 mg dispositivo de libertação intrauterino.	SE/H/1186/001	5566617	BERLEX ESPECIALIDADES FARMACEUTICAS LDA	PT
Jaydess 13,5 mg dispositivo de libertação intrauterino.	SE/H/1186/001	5566625	BERLEX ESPECIALIDADES FARMACEUTICAS LDA	PT
Jaydess® 13,5 mg, intrauterint inlägg	SE/H/1186/001	30387	BAYER OY	FI

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
Jaydess 13,5 mg sistema de liberación intrauterino	SE/H/1186/001	77.169	BAYER HISPANIA SL	ES
Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1186/001	BE433544	BAYER SA NV	BE
Jaydess 13,5 mg, système de diffusion intra-utérin.	SE/H/1186/001	BE433544	BAYER SA NV	BE
Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1186/001	2013040105	BAYER SA NV	LU
Jaydess 13,5 mg intrauterini dostavni sistem	SE/H/1186/001	H/13/00810/001	BAYER D.O.O	SI
Jaydess 13,5 mg intrauterini dostavni sistem	SE/H/1186/001	H/13/00810/002	BAYER D.O.O	SI
Jaydess 13,5 mg sistem cu cedare intrauterină.	SE/H/1186/001	11477/2019/02	BAYER AG	RO
Jaydess 13,5 mg sistem cu cedare intrauterină.	SE/H/1186/001	11477/2019/01	BAYER AG	RO
Jaydess 13.5 mg intrauterine delivery system.	SE/H/1186/001	MA639/02101	BAYER LTD	MT
Jaydess, intrauterint indlæg	SE/H/1186/001	49987	BAYER AB	DK
Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1186/001	1-31748	BAYER AUSTRIA GMBH	AT
Fleree, 13,5 mg intrauteriinne ravivahend	SE/H/1186/001	805513	BAYER AG	EE

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
Jaydess 13,5 mg afleveringsysteem voor intra-uterien gebruik	SE/H/1186/001	BE433544	BAYER SA NV	BE
Jaydess 13,5 mg méhen belüli gyógyszerleadó rendszer	SE/H/1186/001	OGYI-T-22404/01	BAYER AG	HU
Jaydess 13,5 mg intrauterint inlägg	SE/H/1186/001	47317	BAYER AB	SE
Jaydess 13,5 mg leginnlegg	SE/H/1186/001	IS/1/13/001/01	BAYER AB	IS
Jaydess 13,5 mg intrauterinní inzert	SE/H/1186/001	17/049/13-C	BAYER AG	CZ
Jaydess 13.5 mg intrauterine delivery system.	SE/H/1186/001	PA1410/068/001	BAYER LTD	IE
Fleree 13,5 mg vartojimo į gimdos ertmę sistema	SE/H/1186/001	LT/1/13/3219/001	BAYER AG	LT
Fleree 13,5 mg vartojimo į gimdos ertmę sistema	SE/H/1186/001	LT/1/13/3219/002	BAYER AG	LT
Jaydess 13,5 mg intrauterint innlegg	SE/H/1186/001	11-8775	BAYER AB	NO
Jaydess 13,5 mg intrauterinný inzert	SE/H/1186/001	17/0024/13-S	BAYER SPOL SRO	SK
Джейдас 13,5 мг вътрематочна лекарстводоставяща система	SE/H/1186/001	20130075	BAYER AG	BG
Jaydess 13,5 mg depotlääkevalmiste, kohtuun	SE/H/1186/001	30387	BAYER OY	FI
Jaydess 13.5 mg intrauterine delivery system	SE/H/1186/001	PL 00010/0587	BAYER PLC	XI

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
Jaydess® 13,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1186/001	86537.00.00	JENAPHARM GMBH & CO KG	DE
Fleree 13,5 mg intrauterinā sistēma	SE/H/1186/001	13-0048	BAYER AG	LV
Jaydess, 13,5 mg, system terapeutyczny domaciczny.	SE/H/1186/001	21101	BAYER AG	PL
Jaydess 13,5 mg, système de diffusion intra-utérin	SE/H/1186/001	2013040105	BAYER SA NV	LU
JAYDESS 13,5 mg, système de diffusion intra-utérin	SE/H/1186/001	34009 274 194 7 8	BAYER HEALTHCARE	FR
JAYDESS 13,5 mg, système de diffusion intra-utérin	SE/H/1186/001	34009 585 070 8 3	BAYER HEALTHCARE	FR
Jaydess 13,5 mg sistema a rilascio intrauterino	SE/H/1186/001	042522019	BAYER SPA	IT
Jaydess 13,5 mg sistema a rilascio intrauterino	SE/H/1186/001	042522021	BAYER SPA	IT
Мирена 20 микрограма/24 часа вътрематочна лекарстводоставяща система	not available	9800344	BAYER AG	BG
28 mini 30 Mikrogramm überzogene Tabletten	not available	3000361.00.00	JENAPHARM GMBH & CO KG	DE
Mirena 20 mikrogramov/24 hodín intrauterinný inzert	not available	17/0234/99-S	BAYER SPOL SRO	SK
Mirena 20 mikrograma/24 sata intrauterini sustav	not available	HR-H-494254913-01	BAYER DOO	HR

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
Kyleena, intrauterint indlæg	SE/H/1587/001	56994	BAYER AB	DK
Kyleena, 19,5 mg intrauteriinne ravivahend	SE/H/1587/001	922616	BAYER AG	EE
Kyleena 19,5 mg depotlääkevalmiste, kohtuun	SE/H/1587/001	33805	BAYER OY	FI
Kyleena 19,5 mg, intrauterint inlägg	SE/H/1587/001	33805	BAYER OY	FI
Kyleena 19,5 mg intrauterint innlegg	SE/H/1587/001	15-10974	BAYER AB	NO
Kyleena 19,5 mg intrauterint inlägg.	SE/H/1587/001	53746	BAYER AB	SE
Kyleena 19,5 mg, système de diffusion intra-utérin	SE/H/1587/001	BE502000	BAYER SA NV	BE
Kyleena 19,5 mg afleveringsstelsel voor intra-uterien gebruik	SE/H/1587/001	BE502000	BAYER SA NV	BE
Kyleena 19,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1587/001	BE502000	BAYER SA NV	BE
Kyleena 19,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1587/001	137280	BAYER AUSTRIA GMBH	AT
Kyleena 19,5 mg intrauterīna ierīce	SE/H/1587/001	16-0237	BAYER AG	LV
Kyleena, 19,5 mg, system terapeutyczny domaciczny	SE/H/1587/001	23637	BAYER AG	PL
Kyleena 19.5 mg intrauterine delivery system.	SE/H/1587/001	PL 00010/0664	BAYER PLC	XI

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
Kyleena 19,5 mg vartojimo į gimdos ertmę sistema	SE/H/1587/001	LT/1/17/4028/001	BAYER AG	LT
Kyleena 19,5 mg vartojimo į gimdos ertmę sistema	SE/H/1587/001	LT/1/17/4028/002	BAYER AG	LT
Kyleena 19.5 mg intrauterine delivery system	SE/H/1587/001	PA1410/081/001	BAYER LTD	IE
Kyleena 19,5 mg, afleveringsstelsel voor intra-uterien gebruik	SE/H/1587/001	RVG 118462	BAYER BV	NL
Kyleena 19,5 mg intrauterini dostavni sistem	SE/H/1587/001	H/17/02281/001	BAYER D.O.O	SI
Kyleena 19,5 mg intrauterinní inžert	SE/H/1587/001	17/460/16-C	BAYER AG	CZ
Kyleena 19,5 mg sistema de liberación intrauterino	SE/H/1587/001	81.418	BAYER HISPANIA SL	ES
Kyleena 19,5 mg dispositivo de libertação intrauterino	SE/H/1587/001	5694930	BAYER PORTUGAL LDA	PT
Kyleena 19,5 mg dispositivo de libertação intrauterino	SE/H/1587/001	5694948	BAYER PORTUGAL LDA	PT
Kyleena19,5 mg sistema a rilascio intrauterino.	SE/H/1587/001	044756017	BAYER SPA	IT
Kyleena19,5 mg sistema a rilascio intrauterino.	SE/H/1587/001	044756029	BAYER SPA	IT
KyleenaTM 19,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1587/001	96796.00.00	JENAPHARM GMBH & CO KG	DE

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
KYLEENA 19,5 mg, système de diffusion intra-utérin	SE/H/1587/001	34009 300 947 5 4	BAYER HEALTHCARE	FR
KYLEENA 19,5 mg, système de diffusion intra-utérin	SE/H/1587/001	34009 550 334 6 2	BAYER HEALTHCARE	FR
Kyleena 19,5 mg intrauterini dostavni sistem	SE/H/1587/001	H/17/02281/002	BAYER D.O.O	SI
28 mini 30 Mikrogramm überzogene Tabletten	not available	3000361.00.00	JENAPHARM GMBH & CO KG	DE
Mirena 20 Mikrogramm/24 Stunden Intrauterinpessar	not available	1-21529	BAYER AUSTRIA GMBH	AT
Levosert 20 mikrogram/24 timmar intrauterint inlägg	DK/H/3066/001	50571	GEDEON RICHTER PLC.	SE
Levosert 20 Mikrogramm/24 Stunden intrauterines Wirkstofffreisetzungssystem	DK/H/3066/001	91463.00.00	GEDEON RICHTER PLC.	DE
Levosert 20 Mikrogramm/24 Stunden intrauterines Wirkstofffreisetzungssystem	DK/H/3066/001	136091	GEDEON RICHTER PLC.	AT
Levosert, intrauterint indlæg	DK/H/3066/001	53445	GEDEON RICHTER PLC.	DK
Levosert 20 mikrógrömm/24 klst. leginnlegg	DK/H/3066/001	IS/1/15/008/01	GEDEON RICHTER PLC.	IS

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
Benilexa 20 micrograms/24 hours Intrauterine Delivery System	DK/H/3066/001	PL 04854/0157	GEDEON RICHTER PLC.	XI
Levosert 20 mikrogramov/ 24 ur intrauterini dostavni sistem	DK/H/3066/001	H/15/02074/001	GEDEON RICHTER PLC.	SI
Benilexa 20 microgrammi/24 ore sistema a rilascio intrauterino	DK/H/3066/001	043233016	GEDEON RICHTER PLC.	IT
Levosert 20 mikrogramov/ 24 ur intrauterini dostavni sistem	DK/H/3066/001	H/15/02074/002	GEDEON RICHTER PLC.	SI
Levosert 0,02 mg cada 24 horas sistema de liberación intrauterino	DK/H/3066/001	80021	GEDEON RICHTER PLC.	ES
Levosert 20 μικρογραμμάρια/24 ώρες Ενδομήτρια Συσκευή Αποδέσμευσης	DK/H/3066/001	022402	GEDEON RICHTER PLC.	CY
Benilexa 20 microgrammi/24 ore sistema a rilascio intrauterino	DK/H/3066/001	043233028	GEDEON RICHTER PLC.	IT
Mirena 0,02 mg cada 24 horas sistema de liberación intrauterino	PT/H/0100/001	63.158	BAYER HISPANIA SL	ES
Mirena 20 microgramas/24 horas dispositivo de libertação intrauterino	PT/H/0100/001	2477784	BAYER PORTUGAL LDA	PT

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
Mirena, 20 mikrogramów/24 h, system terapeutyczny domaciczny	PT/H/0100/001	11959	BAYER AG	PL
Mirena 20 Mikrogramm/24 Stunden, intrauterines Wirkstofffreisetzungssystem (IUS)	not available	2011051166	BAYER SA NV	LU
Mirena 20 microgrammes / 24 heures, système de diffusion intra-utérin (SIU)	not available	2011051166	BAYER SA NV	LU
Mirena 20 microgrammi/24ore sistema a rilascio intrauterino	not available	029326016	BAYER AG	IT
Mirena 52 mg Intrauterine Delivery System	not available	PA1410/008/001	BAYER LTD	IE
Levonortis 20 microgrammes/24 heures, système de diffusion intra-utérin	BE/H/314/001/DC	BE463626	EXELTIS GERMANY GMBH	BE
Levonortis 20 microgram/24 uur, afleveringsstelsel voor intra-uterien gebruik	BE/H/314/001/DC	BE463626	EXELTIS GERMANY GMBH	BE
Levonortis 20 microgrammes/24 heures, système de diffusion intra-utérin	BE/H/314/001/DC	2015040082	EXELTIS GERMANY GMBH	LU

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
Levonortis 20 microgrammes/24 heures, système de diffusion intra-utérin	BE/H/314/001/DC	2015040082	EXELTIS GERMANY GMBH	LU
Levonortis 20 Mikrogramm/24 Stunden, Intrauterines Wirkstofffreisetzungssystem	BE/H/314/001/DC	BE463626	EXELTIS GERMANY GMBH	BE
Levonortis 20 microgrammes/24 heures, système de diffusion intra-utérin	BE/H/314/001/DC	2015040082	EXELTIS GERMANY GMBH	LU
Levosert One 20 micrograms/24 hours Intrauterine Delivery System	DK/H/3066/002	MA1031/00402	GEDEON RICHTER PLC.	MT
Mirena® , 52 mg, Intrauterinpressar mit Hormonabgabe.	not available	41880.00.00	JENAPHARM GMBH & CO KG	DE
Mirena®, 52mg, Intrauterinpressar mit Hormonabgabe.	not available	30495.00.00	JENAPHARM GMBH & CO KG	DE
Mirena, 20 mikrogrammi/24 tunnis intrauteriinne ravivahend	not available	127696	BAYER AG	EE
Levonorgestrel "Richter", intrauterint indlæg	DK/H/3182/001	64289	GEDEON RICHTER PLC.	DK
Levosert SHI 20 mikrograma/24 sata intrauterini sustav za isporuku	DK/H/3182/001	HR-H-845986671	GEDEON RICHTER PLC.	HR

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
Levosert SHI 20 mikrograma/24 sata intrauterini sustav za isporuku	DK/H/3182/001	HR-H-845986671	GEDEON RICHTER PLC.	HR
Levosert 20 microgramas/24 horas Dispositivo de Libertação Intrauterino	PT/H/2373/001	5762836	GEDEON RICHTER PLC.	PT
Levosert 20 mikrogrammi/24 tunnis intrauteriinne ravivahend	PT/H/2373/001	979519	GEDEON RICHTER PLC.	EE
Levosert 20 mikrograma/24 sata intrauterini sustav za isporuku	PT/H/2373/001	HR-H-896425945	GEDEON RICHTER PLC.	HR
Mirena 20 mikrog/24 timmar intrauterint inlägg	not available	10212	BAYER OY	FI
Mirena 20 mikrog/24 tuntia depotlääkevalmiste, kohtuun	not available	10212	BAYER OY	FI
Mirena 20 Mikrogramm/24 Stunden, intrauterines Wirkstofffreisetzungssystem (IUS)	not available	BE170737	BAYER SA NV	BE
Mirena 20 microgram / 24 uur, afleveringsysteem voor intra-uterien gebruik (IUS)	not available	BE170737	BAYER SA NV	BE

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
Mirena 20 microgrammes / 24 heures, système de diffusion intra-utérin (SIU)	not available	BE170737	BAYER SA NV	BE
Mirena 20 mikrogramov/24 ur intrauterini dostavni sistem	not available	H/99/01031/001	BAYER D.O.O	SI
Mirena® 20 micrograms/24 hours intrauterine delivery system	not available	MA639/02201	BAYER LTD	MT
Mirena 20 mikrógrömm/24 klst. leginnlegg	not available	MTNR 920074 (IS)	BAYER AB	IS
Mirena 52 mg intrauterinní inzert	not available	17/372/97-C	BAYER AG	CZ
Mirena®, ενδομήτριο εξάρτημα απελευθέρωσης λεβονοργεστρέλης, 52 mg/εξάρτημα	not available	18612	BAYER HELLAS SA	CY
Levosert 20 microgram/24 hours Intrauterine Delivery System	HU/H/0580/001	PL 04854/0158	GEDEON RICHTER PLC.	XI
DONASERT 20 micrograme/24 ore sistem cu cedare intrauterină	HU/H/0580/001	11491/2019/01	GEDEON RICHTER ROMÂNIA S.A.	RO
Levosert 20 mikrogramu/24 stundās intrauterīna sistēma	HU/H/0580/001	13-0032	GEDEON RICHTER PLC.	LV

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
ЛЕВОСЕРТ 20 МИКРОГРАМА/24 ЧАСА ВЪТРЕМАТОЧНА ЛЕКАРСТВОДОСТАВЯЩА СИСТЕМА	HU/H/0580/001	20130077	GEDEON RICHTER PLC.	BG
Levosert 20 mikrogramov/24 hodín, intrauterinný inzert	HU/H/0580/001	17/0236/13-S	GEDEON RICHTER PLC.	SK
Levosert 20 mikrogramm/24 óra méhen belüli gyógyszerleadó rendszer	HU/H/0580/001	OGYI-T-22505/01	GEDEON RICHTER PLC.	HU
LEVOSERT 20 mikrogramų / 24 valandų vartojimo į gimdos ertmę sistema	HU/H/0580/001	LT/1/13/3319/001	GEDEON RICHTER PLC.	LT
Levosert 20 mikrogramů/24 hodin, intrauterinní inzert	HU/H/0580/001	17/285/13-C	GEDEON RICHTER PLC.	CZ
Levosert, 52 mg (20 mikrogramów/24 h), system terapeutyczny domaciczny	HU/H/0580/001	21336	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
Mirena® 20 micrograms/24 hours intrauterine delivery system	not available	PL 00010/0547	BAYER PLC	XI
MICROVAL, comprimé enrobé	not available	34009 322 006 7 2	PFIZER HOLDING FRANCE	FR
MICROVAL, comprimé enrobé	not available	34009 322 007 3 3	PFIZER HOLDING FRANCE	FR
Mirena 20 mikrogram/24 timer intrauterint innlegg	not available	7935	BAYER AB	NO

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
Mirena 20 microgramme/24 ore sistem cu cedare intrauterină	not available	7842/2015/01	BAYER AG	RO
Mirena®, ενδομήτριο εξάρτημα απελευθέρωσης λεβονοργεστρέλης, 52 mg/εξάρτημα	not available	20731/1-4-2008	BAYER HELLAS SA	GR
Luadei 13.5 mg intrauterine delivery system	SE/H/1187/001	47573	BAYER AB	SE
Luadei® 13,5 mg intrauterines Wirkstofffreisetzungssystem	SE/H/1187/001	86538.00.00	JENAPHARM GMBH & CO KG	DE
MIRENA 52 mg (20 microgrammes/24 heures), dispositif intra-utérin	not available	34009 339 292 8 2	BAYER HEALTHCARE	FR
Microluton® 30 mikrog - tabletti, päällystetty	not available	6424	BAYER OY	FI
Jadelle® sine inserter 2 x 75 mg implantat	FI/H/0189/001	17098	BAYER OY	FI
Jadelle® sine inserter 2 x 75 mg implantaatit	FI/H/0189/001	17098	BAYER OY	FI
Microlut 30 Mikrogramm überzogene Tabletten	not available	6929492.00.00	JENAPHARM GMBH & CO KG	DE
Levosert 20 microgrammes/24 heures, système de diffusion intra-utérin	BE/H/0313/001	BE446586	CERES PHARMA NV	BE
Levosert 20 microgram/24 uur, afleveringsysteem voor intra-uterien gebruik	BE/H/0313/001	BE446586	CERES PHARMA NV	BE

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
Levosert 20 Mikrogramm/24 Stunden, Intrauterines Wirkstofffreisetzungssystem	BE/H/0313/001	BE446586	CERES PHARMA NV	BE
Levosert 20 microgrammes/24 heures, système de diffusion intra-utérin	UK/H/5491/01/DC	2014060143	CERES PHARMA NV	LU
Levosert 20 Mikrogramm/24 Stunden, Intrauterines Wirkstofffreisetzungssystem	UK/H/5491/001	2014060143	CERES PHARMA NV	LU
Mirena 20 mikg/24 timer intrauterint indlæg	not available	14881	BAYER AB	DK