



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2018  
EMA/798648/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: levonorgestrel

Procedure no.: PSUSA/00001856/201712



| <b>Product Name<br/>(in authorisation country)</b> | <b>MRP/DCP Authorisation<br/>Number</b> | <b>National Authorisation<br/>Number</b> | <b>MAH of product in the<br/>Member State</b> | <b>Member State where<br/>product is authorised</b> |
|----------------------------------------------------|-----------------------------------------|------------------------------------------|-----------------------------------------------|-----------------------------------------------------|
| 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                                                  |
| Escapelle 1500 microgrammi,<br>compressa           | UK/H/0803/001                           | 038802017                                | GEDEON RICHTER PLC.                           | IT                                                  |
| Postinor 1500 Mikrogramm -<br>Tablette             | UK/H/0803/001                           | 1-26693                                  | GEDEON RICHTER PLC.                           | AT                                                  |
| Postinor 1,5 mg tablett                            | UK/H/0803/001                           | 05-3275                                  | GEDEON RICHTER PLC.                           | NO                                                  |
| Postinor 1500 microgram<br>tablet                  | UK/H/0803/001                           | RVG 32253                                | GEDEON RICHTER PLC.                           | NL                                                  |
| Postinor 1500 Mikrogramm<br>Tablette               | UK/H/0803/001                           | 62588.00.00                              | GEDEON RICHTER PLC.                           | DE                                                  |
| Postinor 1,5 mg, tafla                             | UK/H/0803/001                           | IS/I/05/016/01                           | GEDEON RICHTER PLC.                           | IS                                                  |
| Prevenelle 1500 microgram<br>tablet                | UK/H/0803/001                           | PA1330/021/001                           | GEDEON RICHTER PLC.                           | IE                                                  |
| Levonelle® 1500 microgram<br>tablet                | UK/H/0803/001                           | PL 04854/0150                            | GEDEON RICHTER PLC.                           | UK                                                  |
| Postinor 1500 microgrammes<br>comprimé             | UK/H/0803/001                           | BE285196                                 | GEDEON RICHTER PLC.                           | BE                                                  |
| Postinor 1500 microgram<br>tablet                  | UK/H/0803/001                           | BE285196                                 | GEDEON RICHTER PLC.                           | BE                                                  |
| Postinor 1500 Mikrogramm<br>Tabletten              | UK/H/0803/001                           | BE285196                                 | GEDEON RICHTER PLC.                           | BE                                                  |
| Postinor 1,5 mg comprimido                         | UK/H/0803/001                           | 67515                                    | GEDEON RICHTER PLC.                           | ES                                                  |

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| Postinor 1500<br>μικρογραμμάρια δισκίο                                                    | UK/H/0803/001                   | 39664/9-6-2015                   | GEDEON RICHTER PLC.                   | GR                                          |
| Postinor 1500 microgrammes,<br>comprimé                                                   | UK/H/0803/001                   | 2006010037                       | GEDEON RICHTER PLC.                   | LU                                          |
| ESCAPELLE 1,5 mg tabletė                                                                  | UK/H/0803/001                   | LT/1/06/0511/001                 | GEDEON RICHTER PLC.                   | LT                                          |
| Escapelle 1500 mikrogramů<br>tableta                                                      | UK/H/0803/001                   | 17/168/07-C                      | GEDEON RICHTER PLC.                   | CZ                                          |
| Escapelle tabletka 1500<br>mikrogramów, 1500<br>mikrogramów, tabletka                     | UK/H/0803/001                   | 12048                            | GEDEON RICHTER PLC.                   | PL                                          |
| LEVONORGESTREL BIOGARAN<br>1,5 mg, comprimé                                               | UK/H/0803/001                   | 373 075-6                        | GEDEON RICHTER PLC.                   | FR                                          |
| Postinor 1,5 mg tablett                                                                   | UK/H/0803/001                   | 22194                            | GEDEON RICHTER PLC.                   | SE                                          |
| Postinor 1500 microgramas<br>comprimido                                                   | UK/H/0803/001                   | 5693189                          | GEDEON RICHTER PLC.                   | PT                                          |
| Mirena 20 mikrog/24 timmar<br>intrauterint inlägg                                         | not available                   | 10212                            | BAYER OY                              | FI                                          |
| Mirena 20 mikrógrömm/24<br>klst. leginnlegg                                               | not available                   | MTNR 920074 (IS)                 | BAYER AB                              | IS                                          |
| Mirena 20 mikrogram/24<br>timer intrauterint innlegg                                      | not available                   | 7935                             | BAYER AB                              | NO                                          |
| Mirena 20 Mikrogramm/24<br>Stunden, intrauterines<br>Wirkstofffreisetzungssystem<br>(IUS) | not available                   | BE170737                         | BAYER SA NV                           | BE                                          |

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| Mirena 20 Mikrogramm/24<br>Stunden, intrauterines<br>Wirkstofffreisetzungssystem<br>(IUS) | not available                   | 2011051166                       | BAYER SA NV                           | LU                                          |
| Mirena 20 micrograme/24 ore<br>sistem cu cedare intrauterina                              | not available                   | 7842/2015/01                     | BAYER OY                              | RO                                          |
| Mirena                                                                                    | not available                   | 17/0234/99-S                     | BAYER SPOL SRO                        | SK                                          |
| Mirena, 20 mikrogrammi/24<br>tunnis intrauteriinne<br>ravivahend                          | not available                   | 127696                           | BAYER AG                              | EE                                          |
| MIRENA                                                                                    | not available                   | 17/372/97-C                      | BAYER AG                              | CZ                                          |
| Mirena® 20 micrograms/24<br>hours intrauterine delivery<br>system                         | not available                   | MA513/03901                      | BAYER PLC                             | MT                                          |
| Mirena®, ενδομήτριο<br>εξάρτημα απελευθέρωσης<br>λεβονοργεστρέλης, 52<br>mg/εξάρτημα      | not available                   | 18612                            | BAYER HELLAS SA                       | CY                                          |
| Mirena®, 52mg,<br>Intrauterinpessar mit<br>Hormonabgabe                                   | not available                   | 30495.00.00                      | JENAPHARM GMBH & CO KG                | DE                                          |
| Mirena 52 mg Intrauterine<br>Delivery System                                              | not available                   | PA 1410/8/1                      | BAYER LTD                             | IE                                          |

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| Mirena®, ενδομήτριο<br>εξάρτημα απελευθέρωσης<br>λεβονοργεστρέλης, 52<br>mg/εξάρτημα    | not available                   | 20731/1-4-2008                   | BAYER HELLAS SA                       | GR                                          |
| MIRENA 52 mg (20<br>microgrammes/24 heures),<br>dispositif intra-utérin                 | not available                   | 34009 339 292 8 2                | BAYER HEALTHCARE                      | FR                                          |
| Mirena 20 mikrogramov/24 ur<br>intrauterini dostavni sistem                             | not available                   | H/99/01031/001                   | BAYER D.O.O                           | SI                                          |
| Мирена 20 микрограма/24<br>часа вътрематочна<br>лекарстводоставяща<br>система           | not available                   | 9800344                          | BAYER OY                              | BG                                          |
| Mirena®, 52mg,<br>Intrauterinpessar mit<br>Hormonabgabe                                 | not available                   | 41880.00.00                      | JENAPHARM GMBH & CO KG                | DE                                          |
| Mirena® 20 micrograms/24<br>hours intrauterine delivery<br>system                       | not available                   | PL 00010/0547                    | BAYER PLC                             | UK                                          |
| Mirena 20 microgram / 24<br>uur, afleveringsstelsel voor<br>intra-uterien gebruik (IUS) | not available                   | BE170737                         | BAYER SA NV                           | BE                                          |
| Mirena 20 microgrammes / 24<br>heures, système de diffusion<br>intra-utérin (SIU)       | not available                   | BE170737                         | BAYER SA NV                           | BE                                          |
| Mirena 20 mikg/24 timer<br>intrauterint indlæg                                          | not available                   | 14881                            | BAYER AB                              | DK                                          |

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| Mirena 20 mikrog/24 tuntia<br>depotlääkevalmiste, kohtuun                         | not available                   | 10212                            | BAYER OY                                   | FI                                          |
| Mirena 20 mikrogramu/ 24<br>stundās intrauterīna sistēma                          | not available                   | 99-0502                          | BAYER AG                                   | LV                                          |
| Mirena 20 mikrogramų/24<br>valandoms vartojimo į gimdos<br>ertmę sistema          | not available                   | LT/1/98/0172/001                 | BAYER AG                                   | LT                                          |
| Mirena, IUD 20 microgram/24<br>uur                                                | not available                   | RVG 16681                        | BAYER BV                                   | NL                                          |
| Mirena 20<br>microgrammi/24ore sistema a<br>rilascio intrauterino                 | not available                   | 029326016                        | BAYER AG                                   | IT                                          |
| Mirena 20 Mikrogramm/24<br>Stunden Intrauterinpessar                              | not available                   | 1-21529                          | BAYER AUSTRIA GMBH                         | AT                                          |
| Mirena 20 microgrammes / 24<br>heures, système de diffusion<br>intra-utérin (SIU) | not available                   | 2011051166                       | BAYER SA NV                                | LU                                          |
| Mirena 20 mikrogram/24<br>timmar intrauterint inlägg                              | not available                   | 11668                            | BAYER AB                                   | SE                                          |
| Mirena 20 mikrograma/24<br>sata intrauterini sustav                               | not available                   | HR-H-494254913-01                | BAYER DOO                                  | HR                                          |
| Mirena méhen belüli<br>gyógyszerleadó rendszer                                    | not available                   | OGYI-T-6210/01                   | BAYER AG                                   | HU                                          |
| Jaydess 13.5 mg intrauterine<br>delivery system                                   | SE/H/1186/001                   | MA513/05301                      | BAYER PLC                                  | MT                                          |
| Jaydess 13,5 mg dispositivo de<br>libertação intrauterino.                        | SE/H/1186/01                    | 5566617                          | BERLEX ESPECIALIDADES<br>FARMACEUTICAS LDA | PT                                          |

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| Jaydess 13,5 mg dispositivo de libertação intrauterino.   | SE/H/1186/01                    | 5566625                          | BERLEX ESPECIALIDADES FARMACEUTICAS LDA | PT                                          |
| Jaydess 13,5 mg, intrauterint inlägg                      | SE/H/1186/001                   | 30387                            | BAYER OY                                | FI                                          |
| Jaydess 13,5 mg sistema de liberación intrauterino        | SE/H/1186/001                   | 77.169                           | BAYER HISPANIA SL                       | ES                                          |
| Jaydess 13,5 mg sistem cu cedare intrauterină             | SE/H/1186/001                   | 5638/2013/01                     | BAYER AG                                | RO                                          |
| Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem | SE/H/1186/01/DC                 | BE433544                         | BAYER SA NV                             | BE                                          |
| Jaydess 13,5 mg, système de diffusion intra-utérin        | SE/H/1186/01/DC                 | BE433544                         | BAYER SA NV                             | BE                                          |
| Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem | SE/H/1186/01/DC                 | 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                   | 5638/2013/02                     | BAYER AG                                | RO                                          |
| Jaydess                                                   | SE/H/1186/001                   | 49987                            | BAYER AB                                | DK                                          |
| Jaydess 13,5 mg intrauterines Wirkstofffreisetzungssystem | SE/H/1186/01/DC                 | 1-31748                          | BAYER AUSTRIA GMBH                      | AT                                          |
| Fleree, 13,5 mg intrauteriinne ravivahend                 | SE/H/1186/001                   | 805513                           | BAYER AG                                | EE                                          |

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| Jaydess 13,5 mg<br>afleveringsstelsel voor intra-<br>uterien gebruik | SE/H/1186/01/DC                 | BE433544                         | BAYER SA NV                           | BE                                          |
| Jaydess 13,5 mg méhen belüli<br>gyógyszerleadó rendszer              | SE/H/1186/001                   | OGYI-T-22404/01                  | BAYER AG                              | HU                                          |
| Jaydess 13,5 mg intrauterint<br>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<br>inzert                              | SE/H/1186/001                   | 17/049/13-C                      | BAYER AG                              | CZ                                          |
| Jaydess 13.5 mg intrauterine<br>delivery system                      | SE/H/1186/001                   | PA 1410/068/001                  | BAYER LTD                             | IE                                          |
| Fleree 13,5 mg vartojimo į<br>gimdos ertmę sistema                   | SE/H/1186/01/DC                 | LT/1/13/3219/001                 | BAYER PHARMA AG                       | LT                                          |
| Fleree 13,5 mg vartojimo į<br>gimdos ertmę sistema                   | SE/H/1186/01/DC                 | LT/1/13/3219/002                 | BAYER PHARMA AG                       | LT                                          |
| Jaydess 13,5 mg intrauterint<br>innlegg                              | SE/H/1186/001                   | 11-8775                          | BAYER AB                              | NO                                          |
| Jaydess 13,5 mg intrauterinný<br>inzert                              | SE/H/1186/01/DC                 | 17/0024/13-S                     | BAYER SPOL SRO                        | SK                                          |
| Джейдас 13,5 mg<br>вътрематочна<br>лекарстводоставяща<br>система     | SE/H/1186/001                   | 20130075                         | BAYER AG                              | BG                                          |
| Jaydess 13,5 mg<br>depotlääkevalmiste, kohtuun                       | SE/H/1186/001                   | 30387                            | BAYER OY                              | FI                                          |

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| Jaydess 13.5 mg intrauterine<br>delivery system                      | SE/H/1186/001                   | PL 00010/0587                    | BAYER PLC                             | UK                                          |
| Jaydess® 13,5 mg<br>intrauterines<br>Wirkstofffreisetzungssystem     | SE/H/1186/001                   | 86537.00.00                      | JENAPHARM GMBH & CO KG                | DE                                          |
| Fleree 13,5 mg intrauterina<br>ierice                                | SE/H/1186/001                   | 13-0048                          | BAYER AG                              | LV                                          |
| Jaydess 13,5 mg,<br>afleveringsysteem voor intra-<br>uterien gebruik | SE/H/1186/001                   | RVG 111192                       | BAYER BV                              | NL                                          |
| Jaydess, 13,5 mg, system<br>terapeutyczny domaciczny                 | SE/H/1186/001                   | 21101                            | BAYER AG                              | PL                                          |
| Jaydess 13,5 mg, système de<br>diffusion intra-utérin                | SE/H/1186/001                   | 2013040105                       | BAYER SA NV                           | LU                                          |
| JAYDESS 13,5 mg, système de<br>diffusion intra-utérin                | SE/H/1186/01/DC                 | 34009 274 194 7 8                | BAYER HEALTHCARE                      | FR                                          |
| JAYDESS 13,5 mg, système de<br>diffusion intra-utérin                | SE/H/1186/01/DC                 | 34009 585 070 8 3                | BAYER HEALTHCARE                      | FR                                          |
| Jaydess 13,5 mg sistema a<br>rilascio intrauterino                   | SE/H/1186/001                   | 042522019                        | BAYER SPA                             | IT                                          |
| Jaydess 13,5 mg sistema a<br>rilascio intrauterino                   | SE/H/1186/001                   | 042522021                        | BAYER SPA                             | IT                                          |
| Norlevo 1,5 mg comprimido                                            | not available                   | 5607288                          | LABORATOIRE HRA PHARMA                | PT                                          |
| Levonelle-2 750 microgram<br>tablet                                  | UK/H/0363/001                   | PL 04854/0155                    | GEDEON RICHTER PLC.                   | UK                                          |
| Frivelle, tabletter                                                  | DK/H/2357/001                   | 53303                            | ORIFARM GENERICS A/S                  | DK                                          |

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| Postinor-2 750 micrograme<br>comprimata     | not available                   | 8348/2015/01                     | GEDEON RICHTER PLC.                   | RO                                          |
| Escapelle 1,5 mg tableta                    | not available                   | UP/I-530-09/13-02/351            | GEDEON RICHTER PLC.                   | HR                                          |
| ESCAPELLE 1,5 mg<br>comprimata              | not available                   | 8697/2016/01                     | GEDEON RICHTER PLC.                   | RO                                          |
| Постинор-Дуо 750<br>микрограма таблетки     | not available                   | 20000358                         | GEDEON RICHTER PLC.                   | BG                                          |
| Ескапеле 1,5 mg таблетка                    | not available                   | 20060032                         | GEDEON RICHTER PLC.                   | BG                                          |
| Upostelle 1500 microgram<br>tablet          | not available                   | PL04854/0106                     | GEDEON RICHTER PLC.                   | UK                                          |
| Rigesoft 750 mikrogramm<br>tabletta         | not available                   | OGYI-T-6372/01                   | GEDEON RICHTER PLC.                   | HU                                          |
| Escapelle 1,5 mg tablettes                  | not available                   | 04-0318                          | GEDEON RICHTER PLC.                   | LV                                          |
| Escapelle 1,5 mg tablett                    | not available                   | 443104                           | GEDEON RICHTER PLC.                   | EE                                          |
| Escapelle 1,5 mg tabletta                   | not available                   | OGYI-T-9330/01                   | GEDEON RICHTER PLC.                   | HU                                          |
| Escapelle 1,5 mg tableta                    | not available                   | H/08/00568/001                   | GEDEON RICHTER PLC.                   | SI                                          |
| Levonelle One Step 1500<br>microgram tablet | not available                   | PL04854/0151                     | GEDEON RICHTER PLC.                   | UK                                          |
| POSTINOR-DUO 750<br>mikrogrami tablettes    | not available                   | 96-0366                          | GEDEON RICHTER PLC.                   | LV                                          |
| POSTINOR-DUO 750<br>mikrogramų tabletės     | not available                   | LT/1/03/3098/001                 | GEDEON RICHTER PLC.                   | LT                                          |

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| POSTINOR-2 750 mikrogramm<br>tablety              | not available                   | 17/834/99-C                      | GEDEON RICHTER PLC.                   | CZ                                          |
| ESCAPELLE 1500 mikrogramov<br>tableta             | not available                   | 17/0187/04-S                     | GEDEON RICHTER PLC.                   | SK                                          |
| Jadelle® sine inserter 2 x 75<br>mg implantat     | FI/H/0189/001                   | 17098                            | BAYER OY                              | FI                                          |
| Jadelle® sine inserter 2 x 75<br>mg implantaatit  | FI/H/0189/001                   | 17098                            | BAYER OY                              | FI                                          |
| NorLevo 1,5mg comprimido                          | not available                   | 67.770                           | LABORATOIRE HRA PHARMA                | ES                                          |
| Norlevo 750 mikrogram<br>tabletter                | not available                   | MTNR 99-7321                     | LABORATOIRE HRA PHARMA                | NO                                          |
| Norlevo 1,5 mg tabletter                          | not available                   | 05-3426                          | LABORATOIRE HRA PHARMA                | NO                                          |
| PiDaNa 1,5 mg Tablette                            | not available                   | 75074.00.000                     | LABORATOIRE HRA PHARMA                | DE                                          |
| Microluton® 30 mikrog,<br>dragerad tablett        | not available                   | 6424                             | BAYER OY                              | FI                                          |
| Norgeston®                                        | not available                   | 00010/0550                       | BAYER PLC                             | UK                                          |
| Microluton® 30 mikrog -<br>tabletti, päällystetty | not available                   | 6424                             | BAYER OY                              | FI                                          |
| 28 mini 30 Mikrogramm<br>überzogene Tabletten     | not available                   | 3000361.00.00                    | JENAPHARM GMBH & CO KG                | DE                                          |
| Microlut 30 Mikrogramm<br>überzogene Tabletten    | not available                   | 6929492.00.00                    | JENAPHARM GMBH & CO KG                | DE                                          |
| Levonorgestrel 1.5 mg tablet                      | not available                   | PL 39352/0394                    | KOSEI PHARMA UK LIMITED               | UK                                          |

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| Kyleena, intrauterint indlæg                                        | SE/H/1587/001                   | 56994                            | BAYER AB                              | DK                                          |
| Kyleena, 19,5 mg<br>intrauteriinne ravivahend                       | SE/H/1587/001                   | 922616                           | BAYER AG                              | EE                                          |
| Kyleena 19,5 mg<br>depotlääkevalmiste, kohtuun                      | SE/H/1587/001                   | 33805                            | BAYER OY                              | FI                                          |
| Kyleena 19,5 mg, intrauterint<br>inlägg                             | SE/H/1587/001                   | 33805                            | BAYER OY                              | FI                                          |
| Kyleena 19,5 mg intrauterint<br>innlegg                             | SE/H/1587/001                   | 15-10974                         | BAYER AB                              | NO                                          |
| Kyleena 19,5 mg intrauterini<br>sustav                              | SE/H/1587/001                   | HR-H-476936442-01                | BAYER DOO                             | HR                                          |
| Kyleena 19,5 mg intrauterini<br>sustav                              | SE/H/1587/001                   | HR-H-476936442-02                | BAYER DOO                             | HR                                          |
| Kyleena 19,5 mg intrauterint<br>inlägg.                             | SE/H/1587/001                   | 53746                            | BAYER AB                              | SE                                          |
| Kyleena 19,5 mg, système de<br>diffusion intra-utérin.              | SE/H/1587/001                   | BE502000                         | BAYER SA NV                           | BE                                          |
| Kyleena 19,5 mg<br>afleveringsysteem voor intra-<br>uterien gebruik | SE/H/1587/001                   | BE502000                         | BAYER SA NV                           | BE                                          |
| Kyleena 19,5 mg intrauterines<br>Wirkstofffreisetzungssystem        | SE/H/1587/001                   | BE502000                         | BAYER SA NV                           | BE                                          |
| Kyleena 19,5 mg intrauterines<br>Wirkstofffreisetzungssystem        | SE/H/1587/001                   | 137280                           | BAYER AUSTRIA GMBH                    | AT                                          |
| Kyleena 19,5 mg intrauterinný<br>inzert                             | SE/H/1587/001                   | 17/0500/16-S                     | BAYER SPOL SRO                        | SK                                          |

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| Kyleena 19,5 mg intrauterīna<br>ierīce                                | SE/H/1587/001                   | 16-0237                          | BAYER AG                              | LV                                          |
| Kyleena, 19,5 mg, system<br>terapeutyczny domaciczny.                 | SE/H/1587/001                   | 23637                            | BAYER AG                              | PL                                          |
| Kyleena 19.5 mg intrauterine<br>delivery system.                      | SE/H/1587/001                   | PL 00010/0664                    | BAYER PLC                             | UK                                          |
| Kyleena 19,5 mg vartojimo į<br>gimdos ertmę sistema                   | SE/H/1587/001                   | LT/1/17/4028/001                 | BAYER AG                              | LT                                          |
| Kyleena 19,5 mg vartojimo į<br>gimdos ertmę sistema                   | SE/H/1587/001                   | LT/1/17/4028/002                 | BAYER AG                              | LT                                          |
| Kyleena 19.5 mg intrauterine<br>delivery system.                      | SE/H/1587/001                   | PA1410/081/001                   | BAYER LTD                             | IE                                          |
| Kyleena 19,5 mg,<br>afleveringsstelsel voor intra-<br>uterien gebruik | SE/H/1587/001                   | RVG 118462                       | BAYER BV                              | NL                                          |
| Kyleena 19,5 mg intrauterini<br>dostavni sistem                       | SE/H/1587/001                   | H/17/02281/001                   | BAYER D.O.O                           | SI                                          |
| Kyleena 19,5 mg intrauterinní<br>inzert                               | SE/H/1587/001                   | 17/460/16-C                      | BAYER AG                              | CZ                                          |
| Kyleena 19,5 mg sistema de<br>liberación intrauterino                 | SE/H/1587/001                   | 81.418                           | BAYER HISPANIA SL                     | ES                                          |
| Kyleena 19,5 mg dispositivo<br>de libertação intrauterino             | SE/H/1587/001                   | 5694930                          | BAYER PORTUGAL LDA                    | PT                                          |
| Kyleena 19,5 mg dispositivo<br>de libertação intrauterino             | SE/H/1587/001                   | 5694948                          | BAYER PORTUGAL LDA                    | PT                                          |
| Kyleena 19,5 mg sistema a<br>rilascio intrauterino                    | SE/H/1587/001                   | 044756017                        | BAYER SPA                             | IT                                          |

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| Kyleena 19,5 mg sistema a rilascio intrauterino                             | SE/H/1587/001                           | 044756029                                | BAYER SPA                                     | IT                                                  |
| Kyleena® 19,5 mg intrauterines Wirkstofffreisetzungssystem                  | SE/H/1587/001                           | 96796.00.00                              | JENAPHARM GMBH & CO KG                        | DE                                                  |
| 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                                                  |
| Levosert 20 mikrogram/24 timer intrauterint innlegg                         | UK/H/5593/001                           | 13-9909                                  | GEDEON RICHTER PLC.                           | NO                                                  |
| Levosert 20 micrograms/24 hours Intrauterine Delivery System                | UK/H/5593/001                           | MA 1031/00401                            | GEDEON RICHTER PLC.                           | MT                                                  |
| Levosert 20 mikrogram/24 timmar intrauterint inlägg                         | UK/H/5593/001                           | 50571                                    | GEDEON RICHTER PLC.                           | SE                                                  |
| Levosert 20 Mikrogramm/24 Stunden intrauterines Wirkstofffreisetzungssystem | UK/H/5593/001                           | 91463.00.00                              | GEDEON RICHTER PLC.                           | DE                                                  |
| Levosert 20 Mikrogramm/24 Stunden intrauterines Wirkstofffreisetzungssystem | UK/H/5593/001                           | 136091                                   | GEDEON RICHTER PLC.                           | AT                                                  |
| Levosert 52 mg Intrauterine Delivery System                                 | UK/H/5593/001                           | PA 1330/022/001                          | GEDEON RICHTER PLC.                           | IE                                                  |
| Levosert, intrauterint indlæg                                               | UK/H/5593/001                           | 53445                                    | GEDEON RICHTER PLC.                           | DK                                                  |
| Levosert 20 mikrógrömm/24 klst. leginnlegg                                  | UK/H/5593/001                           | IS/1/15/008/01                           | GEDEON RICHTER PLC.                           | IS                                                  |

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| Benilexa 20 micrograms/24<br>hours Intrauterine Delivery<br>System          | UK/H/5593/001                   | PL 04854/0157                    | GEDEON RICHTER PLC.                   | UK                                          |
| Levosert 20 mikrogramov/ 24<br>ur intrauterini dostavni sistem              | UK/H/5593/001                   | H/15/02074/001                   | GEDEON RICHTER PLC.                   | SI                                          |
| Benilexa 20 microgrammi/24<br>ore sistema a rilascio<br>intrauterino        | UK/H/5593/001                   | 043233016                        | GEDEON RICHTER PLC.                   | IT                                          |
| Levosert 20 mikrogramov/ 24<br>ur intrauterini dostavni sistem              | UK/H/5593/001                   | H/15/02074/002                   | GEDEON RICHTER PLC.                   | SI                                          |
| Levosert 0,02 mg cada 24<br>horas sistema de liberación<br>intrauterino     | UK/H/5593/001                   | 80021                            | GEDEON RICHTER PLC.                   | ES                                          |
| Mirena 0,02 mg cada 24 horas<br>sistema de liberación<br>intrauterino       | PT/H/0100/001                   | 63.158                           | BAYER HISPANIA SL                     | ES                                          |
| Mirena 20 microgramas/24<br>horas dispositivo de<br>libertação intrauterino | PT/H/0100/001                   | 2477784                          | BAYER PORTUGAL LDA                    | PT                                          |
| Mirena, 20 mikrogramów/24<br>h, system terapeutyczny<br>domaciczny          | PT/H/0100/001                   | 11959                            | BAYER AG                              | PL                                          |
| Luadei 13.5 mg intrauterine<br>delivery system                              | SE/H/1187/001                   | 47573                            | BAYER AB                              | SE                                          |
| Luadei® 13,5 mg intrauterines<br>Wirkstofffreisetzungssystem                | SE/H/1187/001                   | 86538.00.00                      | JENAPHARM GMBH & CO KG                | DE                                          |
| Jadelle® 2 x 75 mg implantat                                                | FI/H/0128/001                   | 12512                            | BAYER OY                              | FI                                          |

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| Jadelle® 2 x 75 mg -<br>implantaatit       | FI/H/0128/001                   | 12512                            | BAYER OY                              | FI                                          |
| JADELLE 2 x 75 mg implante                 | FI/H/0128/001                   | 5161781                          | BAYER OY                              | PT                                          |
| Levonorgestrel 1.5 mg tablet               | UK/H/5787/001                   | PL 04854/0136                    | GEDEON RICHTER PLC.                   | UK                                          |
| Postinor 1,5 mg tabletti                   | UK/H/5787/001                   | 32491                            | GEDEON RICHTER PLC.                   | FI                                          |
| NORLEVO 1,5 mg compresse                   | FR/H/0146/002                   | 034884078                        | LABORATOIRE HRA PHARMA                | IT                                          |
| NORLEVO 1,5 mg compresse                   | FR/H/0146/002                   | 034884080                        | LABORATOIRE HRA PHARMA                | IT                                          |
| NORLEVO 1,5 mg compresse                   | FR/H/0146/002                   | 034884092                        | LABORATOIRE HRA PHARMA                | IT                                          |
| NORLEVO 1,5 mg compresse                   | FR/H/0146/002                   | 034884104                        | LABORATOIRE HRA PHARMA                | IT                                          |
| NORLEVO 1,5 mg tabletten                   | FR/H/0146/002                   | BE277356                         | LABORATOIRE HRA PHARMA                | BE                                          |
| NORLEVO 1,5 mg, comprimé                   | FR/H/0146/002                   | 34009 565 510 2 6                | LABORATOIRE HRA PHARMA                | FR                                          |
| NORLEVO 1,5 mg, comprimé                   | FR/H/0146/002                   | 34009 565 511 9 4                | LABORATOIRE HRA PHARMA                | FR                                          |
| NORLEVO 1,5 mg, comprimé                   | FR/H/0146/002                   | 34009 565 512 5 5                | LABORATOIRE HRA PHARMA                | FR                                          |
| NORLEVO 1,5 mg, comprimé                   | FR/H/0146/002                   | 34009 565 513 1 6                | LABORATOIRE HRA PHARMA                | FR                                          |
| Norlevo 1,5 mg Tabletten                   | FR/H/0146/002                   | 2005100005                       | LABORATOIRE HRA PHARMA                | LU                                          |

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| NORLEVO® 1,5 mg -tabletti                  | FR/H/0146/002                   | 20803                            | LABORATOIRE HRA PHARMA                | FI                                          |
| NORLEVO 1,5 mg, comprimé                   | FR/H/0146/002                   | 34009 364 137 2 6                | LABORATOIRE HRA PHARMA                | FR                                          |
| Vikela 1,5 mg - Tablette                   | FR/H/0146/002                   | 1-26057                          | LABORATOIRE HRA PHARMA                | AT                                          |
| NorLevo 1,5 mg, tabletten                  | FR/H/0146/002                   | RVG 32303                        | LABORATOIRE HRA PHARMA                | NL                                          |
| Norlevo 1,5 mg comprimés                   | FR/H/0146/002                   | BE277356                         | LABORATOIRE HRA PHARMA                | BE                                          |
| NORLEVO 1,5 mg tabletten                   | FR/H/0146/002                   | BE277356                         | LABORATOIRE HRA PHARMA                | BE                                          |
| Norlevo δισκίο των 1,5 mg                  | FR/H/0146/002                   | 74875/20-12-2012                 | LABORATOIRE HRA PHARMA                | GR                                          |
| NORLEVO 1,5 mg tafla                       | FR/H/0146/002                   | IS/1/05/018/01                   | LABORATOIRE HRA PHARMA                | IS                                          |
| NORLEVO 1.5 mg tablet                      | FR/H/0146/002                   | PA 1166/2/1                      | LABORATOIRE HRA PHARMA                | IE                                          |
| NorLevo, tabletter                         | FR/H/0146/002                   | 37788                            | LABORATOIRE HRA PHARMA                | DK                                          |
| NORLEVO® 1,5 mg -tabletti                  | FR/H/0146/002                   | 20803                            | LABORATOIRE HRA PHARMA                | FI                                          |
| NORLEVO 1,5 mg compresse                   | FR/H/0146/002                   | 034884066                        | LABORATOIRE HRA PHARMA                | IT                                          |
| NORLEVO® 1,5 mg comprimés                  | FR/H/0146/002                   | 2005100005                       | LABORATOIRE HRA PHARMA                | LU                                          |
| NORLEVO 1,5 mg tableta                     | FR/H/0146/002                   | H/10/01127/001-005               | LABORATOIRE HRA PHARMA                | SI                                          |

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| NorLevo 1,5 mg tablett                                             | FR/H/0146/002                   | 22234                            | LABORATOIRE HRA PHARMA                | SE                                          |
| Norlevo 1,5 mg tabletter                                           | not available                   | 05-3426                          | LABORATOIRE HRA PHARMA                | NO                                          |
| Emergency Contraceptive<br>Consilient 1500 microgram<br>tablet     | UK/H/4569/001                   | PL 04854/0105                    | GEDEON RICHTER PLC.                   | UK                                          |
| Ramonna 1500 mikrogramů<br>tableta                                 | UK/H/4569/001                   | 17/126/12-C                      | GEDEON RICHTER PLC.                   | CZ                                          |
| Ramonna 1500 mikrogrami<br>tablete                                 | UK/H/4569/001                   | 12-0131                          | GEDEON RICHTER PLC.                   | LV                                          |
| Ramonna, 1500<br>mikrogramów, tabletki                             | UK/H/4569/001                   | 20088                            | GEDEON RICHTER PLC.                   | PL                                          |
| RAMONNA 1500 micrograme<br>comprimate                              | UK/H/4569/001                   | 4737/2012/01                     | GEDEON RICHTER ROMÂNIA<br>S.A.        | RO                                          |
| Рамона 1500 микрограма<br>таблетка                                 | UK/H/4569/001                   | 20120195                         | GEDEON RICHTER PLC.                   | BG                                          |
| POSTINOR, 1500<br>mikrogrammi tablett                              | UK/H/4569/001                   | 781812                           | GEDEON RICHTER PLC.                   | EE                                          |
| RAMONNA 1500 mikrogramų<br>tabletė                                 | UK/H/4569/001                   | LT/1/12/2856/001                 | GEDEON RICHTER PLC.                   | LT                                          |
| Ramonna 1,5 mg tableta                                             | UK/H/4569/001                   | H/12/01318/001                   | GEDEON RICHTER PLC.                   | SI                                          |
| Postinor-1 1 500 mikrogramov<br>tableta                            | UK/H/4569/001                   | 56/0201/12-S                     | GEDEON RICHTER PLC.                   | SK                                          |
| Levosert 20 micrograms/24<br>hours Intrauterine Delivery<br>System | UK/H/3030/001                   | PL 04854/0158                    | GEDEON RICHTER PLC.                   | UK                                          |

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| Levosert 20 mikrogramu/24<br>stundās intrauterīna sistēma                          | UK/H/3030/001                   | 13-0032                          | GEDEON RICHTER PLC.                   | LV                                          |
| ЛЕВОСЕРТ 20<br>МИКРОГРАМА/24 ЧАСА<br>ВЪТРЕМАТОЧНА<br>ЛЕКАРСТВОДОСТАВЯЩА<br>СИСТЕМА | UK/H/3030/001                   | 20130077                         | GEDEON RICHTER PLC.                   | BG                                          |
| Levosert 20 mikrogramov/24<br>hodín, intrauterinný inzert                          | UK/H/3030/001                   | 17/0236/13-S                     | GEDEON RICHTER PLC.                   | SK                                          |
| Levosert 20 mikrogramm/24<br>óra méhen belüli<br>gyógyszerleadó rendszer           | UK/H/3030/001                   | OGYI-T-22505/01                  | GEDEON RICHTER PLC.                   | HU                                          |
| LEVOSERT 20 mikrogramų /<br>24 valandų vartojimo į gimdos<br>ertmę sistema         | UK/H/3030/001                   | LT/1/13/3319/001                 | GEDEON RICHTER PLC.                   | LT                                          |
| Levosert 20 mikrogramů/24<br>hodin, intrauterinní inzert                           | UK/H/3030/001                   | 17/285/13-C                      | GEDEON RICHTER PLC.                   | CZ                                          |
| Levosert, 52 mg (20<br>mikrogramów/24 h), system<br>terapeutyczny domaciczny       | UK/H/3030/001                   | 21336                            | GEDEON RICHTER POLSKA SP.<br>Z. O.O.  | PL                                          |
| DONASERT 20 micrograme/24<br>ore sistem cu cedare<br>intrauterină                  | UK/H/3030/001                   | 5672/2013/01                     | GEDEON RICHTER ROMÂNIA<br>S.A.        | RO                                          |
| Ezinelle 1.5 mg tablet                                                             | not available                   | PL 04569/1486                    | GENERICS [UK] LIMITED                 | UK                                          |
| Mireffik 20 micrograms/24<br>hours Intrauterine Delivery<br>System                 | UK/H/5666/001                   | PL 34096/0008                    | MITHRA PHARMACEUTICALS<br>SA          | UK                                          |

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| Levonortis 20<br>microgrammes/24 heures,<br>système de diffusion intra-<br>utérin       | UK/H/5666/001                           | BE463626                                 | EXELTIS GERMANY GMBH                          | BE                                                  |
| Levonortis 20 microgram/24<br>uur, afleveringsstelsel voor<br>intra-uterien gebruik     | UK/H/5666/001                           | BE463626                                 | EXELTIS GERMANY GMBH                          | BE                                                  |
| Levonortis 20<br>microgrammes/24 heures,<br>système de diffusion intra-<br>utérin       | UK/H/5666/001                           | 2015040082                               | EXELTIS GERMANY GMBH                          | LU                                                  |
| Levonortis 20 microgram/24<br>uur, afleveringsstelsel voor<br>intra-uterien gebruik     | UK/H/5666/001                           | 2015040082                               | EXELTIS GERMANY GMBH                          | LU                                                  |
| Levonortis 20<br>Mikrogramm/24 Stunden,<br>Intrauterines<br>Wirkstofffreisetzungssystem | UK/H/5666/001                           | BE463626                                 | EXELTIS GERMANY GMBH                          | BE                                                  |
| Levonortis 20<br>Mikrogramm/24 Stunden,<br>Intrauterines<br>Wirkstofffreisetzungssystem | UK/H/5666/001                           | 2015040082                               | EXELTIS GERMANY GMBH                          | LU                                                  |
| Levosert 20<br>microgrammes/24 heures,<br>système de diffusion intra-<br>utérin         | UK/H/5491/001                           | BE446586                                 | MITHRA PHARMACEUTICALS<br>SA                  | BE                                                  |

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| Levosert 20 microgram/24<br>uur, afleveringsysteem voor<br>intra-uterien gebruik   | UK/H/5491/001                   | BE446586                         | MITHRA PHARMACEUTICALS<br>SA          | BE                                          |
| Levosert 20 Mikrogramm/24<br>Stunden, Intrauterines<br>Wirkstofffreisetzungssystem | UK/H/5491/001                   | BE446586                         | MITHRA PHARMACEUTICALS<br>SA          | BE                                          |
| Levosert 20<br>microgrammes/24 heures,<br>système de diffusion intra-<br>utérin    | UK/H/5491/01/DC                 | 2014060143                       | MITHRA PHARMACEUTICALS<br>SA          | LU                                          |
| Levosert 20 Mikrogramm/24<br>Stunden, Intrauterines<br>Wirkstofffreisetzungssystem | UK/H/5491/001                   | 2014060143                       | MITHRA PHARMACEUTICALS<br>SA          | LU                                          |
| Tresovelle 20 micrograms/24<br>hours Intrauterine Delivery<br>System               | UK/H/5491/001                   | PL 34096/0007                    | MITHRA PHARMACEUTICALS<br>SA          | UK                                          |
| Norlevo δισκίο των 1,5 mg                                                          | not available                   | 20222                            | LABORATOIRE HRA PHARMA                | CY                                          |