



26 July 2017
EMA/344487/2014 correction 2*
Patient Health Protection

List of combined hormonal contraceptives containing chlormadinone in the European Union

| Name of the product | INN | Marketing Authorisation Holder | Country where product is authorised |
|---|--|--------------------------------------|-------------------------------------|
| Bilinda 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Gynial GmbH | Austria |
| Delia 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Kwizda Pharma GmbH | Austria |
| Madinette 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Dermapharm GmbH | Austria |
| Mellow ratiopharm 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Teva Pharma BV | Austria |
| Angiletta 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Actavis Group PTC ehf | Austria |
| Balanca 0.03 mg/2 mg - Filmtabletten | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Austria |
| Beatrice 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Pfizer Corporation Austria GmbH | Austria |
| Belara 0.03 mg/2 mg - Filmtabletten | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Austria |
| Bellissima 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Madaus GmbH | Austria |
| Ethinylestradiol/Chlor madinon Hexal 0.03 mg/2 mg - Filmtabletten | Chlormadinone Ethinylestradiol | Hexal GmbH | Austria |
| BELLINA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Belgium |
| HELEN | Chlormadinone Ethinylestradiol | Mithra Pharmaceuticals S.A. | Belgium |
| MADINELLE | Chlormadinone Ethinylestradiol | Mibe GmbH Arzneimittel | Belgium |
| ORCHIDEA | Chlormadinone Ethinylestradiol | Madaus GmbH | Belgium |
| BELARA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Czech Republic |
| BONISSA 0.03 MG/2 MG POTAHOVANÉ TABLETY | Chlormadinone Ethinylestradiol | Stada Arzneimittel AG | Czech Republic |
| CLORMETIN 2 MG/0.03 MG | Chlormadinone Ethinylestradiol | WH-Pharma s.r.o. | Czech Republic |
| ESETE 2 MG/0.03 MG | Chlormadinone Ethinylestradiol | Teva Pharmaceuticals CR, s.r.o. | Czech Republic |
| FLAYA 0.030 MG/2 MG POTAHOVANÉ TABLETY | Chlormadinone Ethinylestradiol | Heaton k.s. | Czech Republic |
| MADINELLE 0.03 MG/2 MG | Chlormadinone Ethinylestradiol | Mibe GmbH Arzneimittel | Czech Republic |
| BELARA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Estonia |
| CLORMETIN 2 MG/0.03 MG | Chlormadinone Ethinylestradiol | Ladee Pharma Baltics UAB | Estonia |
| Balanca | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | France |
| Balancacontinú | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | France |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | France |
| Belaracontinú | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | France |
| Chlormadinone Ethinylestradiol Actavis 2 mg/0.03 mg | Chlormadinone Ethinylestradiol | Arrow génériques SAS | France |
| Bonita AL 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Allud Pharma GmbH | Germany |
| Angiletta 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Actavis Group PTC ehf | Germany |
| Balanca | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Beatrice 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Pfizer Pharma GmbH | Germany |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Belara 21+7 | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Bellissima | Chlormadinone Ethinylestradiol | Madaus GmbH | Germany |
| Bellissima 0.03 mg/2 mg filmtabletten | Chlormadinone Ethinylestradiol | Madaus GmbH | Germany |
| Bilmon - 1 A Pharma 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | 1 A Pharma GmbH | Germany |
| Chantal | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Chariva | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Chariva 21+7 | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Chloee | Chlormadinone Ethinylestradiol | Zentiva Pharma GmbH | Germany |
| Enriqa | Chlormadinone Acetate Ethinylestradiol | Jenapharm GmbH & Co. KG | Germany |
| Eufem 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Sandoz Pharmaceuticals GmbH | Germany |
| LaBibiane | Chlormadinone Ethinylestradiol | TEVA GmbH | Germany |
| Lilia 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Aristo Pharma GmbH | Germany |
| Lisa | Chlormadinone Ethinylestradiol | Madaus GmbH | Germany |
| Lisette 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Mylan dura gmbH | Germany |
| Madinette 30 | Chlormadinone Ethinylestradiol | Mibe GmbH Arzneimittel | Germany |
| Minette 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Dr. Kade Pharmazeutische Fabrik GmbH | Germany |
| Mona HEXAL 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Hexal Aktiengesellschaft | Germany |
| Neo - Eunomin | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Pink Luna 0.03 mg/2 mg Filmtabletten | Chlormadinone Ethinylestradiol | Stadapharm GmbH | Germany |
| Solera 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Hormosan Pharma GmbH | Germany |
| Bellissima 21+7 | Chlormadinone Ethinylestradiol | Madaus GmbH | Germany |

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|---|---|--|-------------------------------------|
| Verana - ratiopharm 2 mg/0.03 mg Filmtabletten | Chlormadinone Ethinylestradiol | Ratiopharm GmbH | Germany |
| Zetidine ** | Chlormadinone Ethinylestradiol | Mithra Pharmaceuticals S.A. | Germany |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Germany |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Hungary |
| Claranette - ratiopharm | Chlormadinone Ethinylestradiol | Ratiopharm GmbH | Hungary |
| Clormetin | Chlormadinone Ethinylestradiol | Laboratorios Leon Farma SA | Hungary |
| TYARENA | Chlormadinone Ethinylestradiol | Teva Italia S.r.l. | Italy |
| BELARA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Italy |
| EVE | Chlormadinone Ethinylestradiol | Sandoz Spa | Italy |
| CLORETINYL | Chlormadinone Ethinylestradiol | Ratiopharm GmbH | Italy |
| CLORMADINONE ETINILESTRADIOLO MYLAN | Chlormadinone Ethinylestradiol | Mylan S.p.A. | Italy |
| NAVEEN | Chlormadinone Ethinylestradiol | EG S.p.A. | Italy |
| Clormetin 2 mg/0.03 mg film - coated tablets | Chlormadinone Ethinylestradiol | UAB Ladee Pharma Baltics | Latvia |
| Belara 0.03 mg/2 mg film - coated tablets | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Latvia |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Lithuania |
| Bellina | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Luxembourg |
| Bellissima | Chlormadinone Ethinylestradiol | Madaus GmbH | Luxembourg |
| Helen | Chlormadinone Ethinylestradiol | Mithra Pharmaceuticals S.A. | Luxembourg |
| Verana - ratiopharm | Chlormadinone Ethinylestradiol | Ratiopharm GmbH | Luxembourg |
| Madinette | Chlormadinone Ethinylestradiol | Sun-Farm Sp. z o.o. | Poland |
| Angiletta | Chlormadinone Ethinylestradiol | Actavis Group PTC ehf | Poland |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Portugal |
| Bonae | Chlormadinone Ethinylestradiol | Laboratorios Leon Farma SA | Portugal |
| Clarissa | Chlormadinone Ethinylestradiol | Italfarmaco - Produtos Farmacéuticos, Lda. | Portugal |
| Jeniasta | Chlormadinone Ethinylestradiol | Actavis Group PTC ehf | Portugal |
| Libelli | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Portugal |
| BELARA | Chlormadinone Ethinylestradiol | Gedeon Richter România S.A. | Romania |
| TYARENA 200 micrograme/30 micrograme | Chlormadinone Ethinylestradiol | Teva Pharmaceuticals S.R.L. | Romania |
| Angiletta 2 mg /0.03 mg | Chlormadinone Ethinylestradiol | Actavis Group PTC ehf | Slovak Republic |
| Belara | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Slovak Republic |
| Belissa | Chlormadinone Ethinylestradiol | Stada Arzneimittel AG | Slovak Republic |
| Egretta 2 mg/0.03 mg | Chlormadinone Ethinylestradiol | Ratiopharm GmbH | Slovak Republic |
| Ethinylestradiol 0.03 mg/Chlormadinonumacet at 2 mg mibe filmom obalene tablety | Chlormadinone Ethinylestradiol | Mibe GmbH Arzneimittel | Slovak Republic |
| Belara 0.03 mg/2 mg filmsko obložene tablete | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Slovenia |
| BALIANCA 0.03 mg/2mg COMPRIMIDOS RECUBIERTOS CON PELICULA | Chlormadinone Ethinylestradiol | FAES FARMA, S.A. | Spain |
| BALIANCA DIARIO 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA | Chlormadinone Ethinylestradiol | FAES FARMA, S.A. | Spain |
| BELARA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Spain |
| BELARA DIARIO 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA | Chlormadinone Ethinylestradiol | Gedeon Richter Plc. | Spain |
| ELYNOR 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | Chlormadinone Ethinylestradiol | BRILL PHARMA, S.L. | Spain |
| ETINILESTRADIOL/CL ORMADINONA STADA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | Chlormadinone Ethinylestradiol | LABORATORIO STADA, S.L. | Spain |
| ETINILESTRADIOL/CL ORMADINONA CINFA 0.03 mg/2 mg comprimidos recubiertos con película EFG | Chlormadinone Ethinylestradiol | LABORATORIOS CINFA, S.A. | Spain |
| ETINILESTRADIOL/CL ORMADINONA MADDAUS 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG | Chlormadinone Ethinylestradiol | MADDAUS GmbH | Spain |

* This annex was previously amended on 28 June 2017.

** Zetidine has been removed from this list following the withdrawal of its marketing authorisation.