

27 September 2017  
EMA/344487/2014 correction 3\*  
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	Gynlal 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
<b>MADINELLE **</b>	<b>Chlormadinone Ethinylestradiol</b>	<b>Mibe GmbH Arzneimittel</b>	<b>Belgium</b>
ORCHIDEA	Chlormadinone Ethinylestradiol	Madaus GmbH	Belgium
BELARA	Chlormadinone Ethinylestradiol	Gedeon Richter Plc.	Czech Republic
BONISSA 0.03 MG/2 MG POTAHOVANE 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 POTAHOVANE TABLETY	Chlormadinone Ethinylestradiol	Heaton k.s.	Czech Republic
<b>MADINELLE 0.03 MG/2 MG **</b>	<b>Chlormadinone Ethinylestradiol</b>	<b>Mibe GmbH Arzneimittel</b>	<b>Czech Republic</b>
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
LaBiblane	Chlormadinone Ethinylestradiol	TEVA GmbH	Germany
Lilla 0.03 mg/2 mg Filmtabletten	Chlormadinone Ethinylestradiol	Aristo Pharma GmbH	Germany
Lisa	Chlormadinone Ethinylestradiol	Madaus GmbH	Germany

Name of the product	INN	Marketing Authorisation Holder	Country where product is authorised
Lisette 0.03 mg/2 mg Filmtabletten	Chlormadinone Ethinylestradiol	Mylan dura qmbH	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
Verana - ratiopharm 2 ma/0.03 mg Filmtabletten	Chlormadinone Ethinylestradiol	Ratiopharm GmbH	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
Libeli	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
<b>Ethinylestradiol 0.03 mg/Chlormadinoneumacetat 2 mg mibe filmom obalene tablety</b>	<b>Chlormadinone Ethinylestradiol</b>	<b>Mibe GmbH Arzneimittel</b>	<b>Slovak Republic</b>
Belara 0.03 mg/2 mg filmso 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 MADAUS 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	Chlormadinone Ethinylestradiol	MADAUS GmbH	Spain

\* This annex was previously amended on 26 July 2017.

\*\* These products have been withdrawn, therefore they are removed from this list.