



28 June 2017
EMA/344487/2014 corr*
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

Name of the product	INN	Marketing Authorisation Holder	Country where product is authorised
Verana - ratiopharm 2 mg/0.03 mg Filmtabletten	Chlormadinone Ethinylestradiol	Ratiopharm GmbH	Germany
Zetdinone	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
Jenlasta	Chlormadinone Ethinylestradiol	Actavis Group PTC ehf	Portugal
Libell	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
ANGILETTA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG **	Chlormadinone Ethinylestradiol	Actavis Group PTC ehf	Spain
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
TEYDA 0.03 mg/ 2 mg comprimidos recubiertos con película EFG **	Chlormadinone Ethinylestradiol	Pharmacia Grupo Pfizer S.L.	Spain
ETINILESTRADIOL/CL ORMADINONA STADA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG	Chlormadinone Ethinylestradiol	LABORATORIO STADA, S.L.	Spain
TYARENA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG **	Chlormadinone Ethinylestradiol	TEVA PHARMA S.L.U.	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 25 June 2014.

** ANGILETTA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG, TEYDA 0.03 mg/ 2 mg comprimidos recubiertos con película EFG and TYARENA 0.03 mg/2 mg COMPRIMIDOS RECUBIERTOS CON PELICULA EFG have been removed from this list since their authorisations have been revoked in Spain.