



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Annex A and Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for medicinal products containing nomegestrol or medicinal products containing chlormadinone

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1510

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Please note that this draft Annex A and Annex I may be updated during the procedure to reflect any amended information on concerned products/MAHs.



**Annex A**  
**Centrally authorised medicinal products**

<b>MA (EU) Number</b>	<b>(Invented) Name</b>	<b>Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>	<b>Immediate Packaging</b>	<b>Pack Size</b>
EU/1/11/690/001	Zoely	2.5 mg / 1.5 mg	Film-coated tablet	Oral use	blister (PVC/alu)	28 tablets (24 active + 4 placebo)
EU/1/11/690/002	Zoely	2.5 mg / 1.5 mg	Film-coated tablet	Oral use	blister (PVC/alu)	84 tablets (72 active + 12 placebo)
EU/1/11/690/003	Zoely	2.5 mg / 1.5 mg	Film-coated tablet	Oral use	blister (PVC/alu)	168 tablets (144 active + 24 placebo)
EU/1/11/690/004	Zoely	2.5 mg / 1.5 mg	Film-coated tablet	Oral use	blister (PVC/alu)	364 tablets (312 active + 52 placebo)

**Annex I**  
**Nationally authorised medicinal products containing nomegestrol**

<b>Member State in EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Product Name</b>	<b>INN/Active Substance + Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Belgium	Ceres Pharma Nv	Nogest	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Belgium	Stragen Nordic A/S	Nomegestrol Stragen	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Belgium	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Belgium	Theramex Ireland Limited	Naemis	Estradiol Hemihydrate 1.55mg Tablet   Nomegestrol Acetate 3.75mg Tablet, Estradiol Hemihydrate 1.55mg Tablet	Tablet	Oral Use
France	Arrow Generiques	Nomegestrol Arrow	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Biogaran	Nomegestrol Biogaran	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Eg Labo Laboratoires Eurogenerics	Nomegestrol Eg	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Mylan S.A.S	Nomegestrol Mylan	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Sandoz	Nomegestrol Sandoz	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 3.75mg Tablet	Tablet	Oral Use
France	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
France	Theramex Ireland Limited	Naemis	Estradiol Hemihydrate 1.55mg Tablet   Nomegestrol Acetate 3.75mg Tablet, Estradiol Hemihydrate 1.55mg Tablet	Tablet	Oral Use
Italy	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use

<b>Member State in EEA</b>	<b>Marketing Authorisation Holder</b>	<b>Product Name</b>	<b>INN/Active Substance + Strength</b>	<b>Pharmaceutical Form</b>	<b>Route of Administration</b>
Italy	Theramex Ireland Limited	Naemis	Estradiol Hemihydrate 1.55mg Tablet   Nomegestrol Acetate 3.75mg Tablet, Estradiol Hemihydrate 1.55mg Tablet	Tablet	Oral Use
Luxembourg	Ceres Pharma Nv	Nogest	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Luxembourg	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Luxembourg	Theramex Ireland Limited	Naemis	Estradiol Hemihydrate 1.55mg Tablet   Nomegestrol Acetate 3.75mg Tablet, Estradiol Hemihydrate 1.55mg Tablet	Tablet	Oral Use
Poland	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Theramex Ireland Limited	Lutenyl	Nomegestrol Acetate 5mg Tablet	Tablet	Oral Use

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### Nationally authorised medicinal products containing chlormadinone

Member State in EEA	Marketing Authorisation Holder	Product Name	INN/Active Substance + Strength	Pharmaceutical Form	Route of Administration
Austria	Dermapharm Gmbh	Madinette	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Austria	Gedeon Richter Plc.	Balanca	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Austria	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Austria	Gynial Gmbh	Bilinda Gynial	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Austria	Kwizda Pharma Gmbh	Delia	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Belgium	Ceres Pharma Nv	Helen	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Belgium	Gedeon Richter Plc.	Bellina	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Belgium	S.A. Meda Pharma N.V.	Orchidea	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Bulgaria	Gedeon Richter Plc.	Белара 21+7	Chlormadinone Acetate 2mg, Ethinylestradiol 0.03mg   Lactose Monohydrate 94.44mg	Film-Coated Tablet	Oral Use
Croatia	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Croatia	Mibe Pharmaceuticals D.O.O.	Estal	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Czech Republic	Aristo Pharma Gmbh (Art 57)	Clormetin	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Czech Republic	Exeltis Czech S.R.O.	Lydely	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use

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Czech Republic	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Czech Republic	Heaton K.S.	Flaya	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 30µg Tablet	Coated Tablet	Oral Use
Czech Republic	Stada Arzneimittel Ag	Bonissa	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Estonia	Uab Exeltis Baltics	Clormetin	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol Ph. Eur. 0.03mg Tablet	Film-Coated Tablet	Oral
France	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
France	Gedeon Richter Plc.	Belaracontinuo	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.3mg Tablet	Film-Coated Tablet	Oral Use
France	Mylan S.A.S	Chlormadinone Mylan	Chlormadinone Acetate 10mg Tablet	Tablet	Oral Use
France	Mylan S.A.S	Chlormadinone Mylan	Chlormadinone Acetate 5mg Tablet	Tablet	Oral Use
France	Sandoz	Chlormadinone Sandoz	Chlormadinone Acetate 10mg Tablet	Tablet	Oral Use
France	Sandoz	Chlormadinone Sandoz	Chlormadinone Acetate 5mg Tablet	Tablet	Oral Use
France	Sanofi-Aventis France	Luteran	Chlormadinone Acetate 10mg Tablet	Tablet	Oral Use
France	Sanofi-Aventis France	Luteran	Chlormadinone Acetate 5mg Tablet	Tablet	Oral Use
France	Teva Santé	Chlormadinone Teva	Chlormadinone Acetate 10mg Tablet	Tablet	Oral Use
France	Teva Santé	Chlormadinone Teva	Chlormadinone Acetate 5mg Tablet	Tablet	Oral Use

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Germany	Acis Arzneimittel Gmbh	Madinance	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Aliud Pharma Gmbh	Bonita	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Aristo Pharma Gmbh (Art 57)	Lilia	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Besins Healthcare Germany Gmbh	Minette	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Balanca	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Belara 21+7	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.3mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Chariva	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Chariva 21+7	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.3mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Ethinylestradiol/Chlormadinonacetat 21+7 Richter	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 94.44mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Ethinylestradiol/Chlormadinonacetat Richter	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Neo-Eunomin	Chlormadinone Acetate 1mg Tablet, Ethinylestradiol 0.05mg Tablet	Film-Coated Tablet	Oral Use
Germany	Gedeon Richter Plc.	Neo-Eunomin	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.05mg Tablet	Film-Coated Tablet	Oral Use
Germany	Hexal Ag	Mona	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use

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Germany	Hormosan Pharma Gmbh	Solera	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Chlormadinon Jenapharm	Chlormadinone Acetate 2mg Tablet	Tablet	Oral Use
Germany	Jenapharm Gmbh & Co Kg	Enriqa	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Meda Pharma Gmbh & Co. Kg	Bellissima	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Meda Pharma Gmbh & Co. Kg	Bellissima 21+7	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Mibe Gmbh Arzneimittel	Madinette	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Mylan Germany Gmbh	Lisette	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Puren Pharma Gmbh & Co. Kg	Angiletta	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Stadapharm Gmbh	Pink Luna	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Germany	Zentiva Pharma Gmbh	Chloee	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Greece	Elpen Pharmaceutical Co. Inc.	Labous	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Hungary	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Italy	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Italy	Gedeon Richter Plc.	Lybella	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use



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Italy	Mylan S.P.A.	Mytulip	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Italy	Sandoz S.P.A.	Eve	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Latvia	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Latvia	Uab Exeltis Baltics	Clormetin	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol Ph. Eur. 0.03mg Tablet	Film-Coated Tablet	Oral
Lithuania	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 30µg Tablet	Film-Coated Tablet	Oral Use
Luxembourg	Ceres Pharma Nv	Helen	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Luxembourg	Gedeon Richter Plc.	Bellina	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Luxembourg	Meda Pharma Gmbh & Co. Kg	Bellissima	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Poland	Actavis Group Ptc Ehf.	Angiletta	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Poland	Exeltis Poland Sp. Z O.O.	Clormetin	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Poland	Gedeon Richter Polska Sp. Z. O.O.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Poland	Sun-Farm Sp. Z.O.O.	Madinette	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Poland	Symphar Sp. Z O.O.	Symbella	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Portugal	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use

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Portugal	Gedeon Richter Plc.	Chariva	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Portugal	Gedeon Richter Plc.	Libeli	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Portugal	Itf Farmahealth, Produtos Farmacêuticos, Lda	Clarissa	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Portugal	Laboratorios León Farma, S.A.	Bonae	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Romania	Gedeon Richter România S.A.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Romania	Gedeon Richter România S.A.	Belara Continu	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.32mg Tablet	Film-Coated Tablet	Oral Use
Slovakia	Exeltis Slovakia	Lydely	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Slovakia	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Slovakia	Stada Arzneimittel Ag	Belissa	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Slovenia	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Aristo Pharma Iberia, S.L.	Clormadinona/Etiniles triadiol Aristo	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Brill Pharma, S.L.	Elynor	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Gedeon Richter Plc.	Balianca	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Gedeon Richter Plc.	Balianca Diario	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.3mg Tablet	Film-Coated Tablet	Oral Use

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Spain	Gedeon Richter Plc.	Belara	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Gedeon Richter Plc.	Belara Diario	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet   Lactose Monohydrate 97.3mg Tablet	Film-Coated Tablet	Oral Use
Spain	Laboratorio Stada, S.L.	Clormadinona/Etiniles tradiol Stadafarma	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use
Spain	Laboratorio Stada, S.L.	Etinilestradiol/Clorma dinona Stada	Chlormadinone Acetate 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral Use

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