

Annex I

List of nationally authorised medicinal products

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Actavis Group Ptc Ehf.	Sienima	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Dermapharm Gmbh	Dienovel	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Exeltis Germany Gmbh	Dienorette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Exeltis Germany Gmbh	Viola	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Madaus Gmbh	Kappanogest	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Ratiopharm Arzneimittel Vertriebs-Gmbh	Motion	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Austria	Ratiopharm Arzneimittel Vertriebs-Gmbh	Motion Ratiopharm	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Belgium	Effik Benelux	Dienobel	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Belgium	Exeltis Germany Gmbh	Serisima Continu	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Placebo 0mg Tablet	Film-Coated Tablet	Oral use
Bulgaria	Pharmaswiss česká Republika S.R.O.	диенил	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Actavis Group Ptc Ehf.	Sienima	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Bayer Pharma Ag	Jeanine	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Czech Republic	Egis Pharmaceuticals Plc	Omisson	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Egis Pharmaceuticals Plc	Omisson Daily	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Lactose Monohydrate 55mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Exeltis Czech S.R.O.	Diecyclen	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Placebo 0mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Exeltis Magyarország Kft.	Dienille	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Gedeon Richter Plc.	Mistra	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Genericon, S.R.O.	Paoletta	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Sandoz S.R.O.	Foxinette Neo	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Teva Pharmaceuticals Cr, S.R.O.	Verezana	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Czech Republic	Zentiva, K.S.	Bonadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Estonia	Bayer Pharma Ag	Jeanine	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Estonia	Gedeon Richter Plc.	Sibilla Plus	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Lactose Anhydrous 37.26mg Tablet	Film-Coated Tablet	Oral use
Estonia	Laboratorios León Farma, S.A.	Diener	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Estonia	Ladee Pharma Baltics Uab	Lasca	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Estonia	Uab "exeltis Baltics"	Diecyclen	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Germany	1 A Pharma Gmbh	Amelie	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Acis Arzneimittel Gmbh	Dienogenance	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Actavis Group Ptc Ehf.	Aurovida	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Aristo Pharma Gmbh (Art 57)	Aristelle	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Dr. Kade - Besins Pharma Gmbh	Finic	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Tablet	Oral use
Germany	Egis Pharmaceuticals Plc	Omisson	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Emra-Med Arzneimittel Gmbh	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Eurimpharm Arzneimittel Gmbh	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Exeltis Germany Gmbh	Velafee	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Exeltis Germany Gmbh	Velafee 21+7	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Lactose Monohydrate 55.5mg Tablet	Film-Coated Tablet	Oral use
Germany	Hexal Ag	Starletta	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Hormosan Pharma Gmbh	Luvyna	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Jenapharm Gmbh & Co Kg	Maxim	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Jenapharm Gmbh & Co Kg	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Kohlpharma Gmbh	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Laboratorios León Farma, S.A.	Dande	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Laboratorios León Farma, S.A.	Lasca	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Laboratorios León Farma, S.A.	Raener	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Meda Pharma Gmbh & Co. Kg	Kappanogest	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Mibe Gmbh Arzneimittel	Dienovel	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Mibe Gmbh Arzneimittel	Ethinylestradiol / Dienogest Mibe	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Mithra Pharmaceuticals Sa	Midien	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Orifarm Gmbh	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Pharma Gerke Arzneimittelvertriebs Gmbh	Valette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Germany	Ratiopharm Gmbh	Velvet	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Ratiopharm Gmbh	Velvet-Ratiopharm	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Teva Gmbh	Laviola	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Germany	Zentiva Pharma	Bonadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Actavis Group Ptc Ehf.	Sienima	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Alvogen Ipco S.Ar.L	Dande	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Alvogen Ipco S.Ar.L	Diedita	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Lactose Monohydrate 60.9mg Tablet	Film-Coated Tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Omisson	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Omisson Daily	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Exeltis Magyarország Kft.	Dienille	Dienogest 2mg Tablet, Ethinylestradiol 0.03 mg Tablet	Film-Coated Tablet	Oral use
Hungary	Gedeon Richter Plc.	Mistral	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Hungary	Gedeon Richter Plc.	Mistral Continuous	Dienogest 2mg, Ethinylestradiol 0.03mg \$ Lactose Anhydrous 37.26mg	Film-Coated Tablet	Oral use
Hungary	Pharmaswiss česká Republika S.R.O.	Combipat	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Latvia	Bayer Pharma Ag	Jeanine	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Latvia	Exeltis Baltics Uab, Lithuania	Diecyclen	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Latvia	Exeltis Baltics Uab, Lithuania	Diecyclen	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Latvia	Laboratorios Leon Farma, S.A., Spain	Diener	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Latvia	Ladee Pharma Baltics Uab, Lithuania	Lasca	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Latvia	Zentiva, K.S.	Zenadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Lithuania	Bayer Pharma Ag	Jeanine	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Lithuania	Zentiva, K.S.	Zenadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Luxembourg	Mithra Pharmaceuticals Sa	Deltanogest	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Luxembourg	Ratiopharm Gmbh	Velvet	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Luxembourg	Ratiopharm Gmbh	Velvet-Ratiopharm	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Poland	Alvogen Ipco S.Ar.L	Diener	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Poland	Dr. Kade Pharmazeutische Fabrik Gmbh	Dionelle	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Tablet	Oral use
Poland	Egis Pharmaceuticals Plc	Omisson	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Poland	Egis Pharmaceuticals Plc	Omisson Daily	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Poland	Exeltis Poland Sp. Z O.O.	Atywia	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Gedeon Richter Polska Sp. Z. O.O.	Sibilla	Dienogest 2mg, Ethinylestradiol 0.03mg	Film-Coated Tablet	Oral use
Poland	Sun-Farm Sp. Z.O.O.	Dorin	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Poland	Zentiva, K.S.	Bonadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Portugal	Aurovitas Unipessoal, Lda.	Sienima	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Romania	Gedeon Richter România S.A.	Sibilla	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Romania	Gedeon Richter România S.A.	Sibilla Zilnic	Dienogest 2mg, Ethinylestradiol 0.03mg \$ Lactose Anhydrous 37.26mg	Film-Coated Tablet	Oral use
Romania	Pharmaswiss česká Republika S.R.O.	Dienille	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Romania	Zentiva, K.S.	Zenadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Bayer Pharma Ag	Jeanine	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Coated Tablet	Oral use
Slovakia	Egis Pharmaceuticals Plc	Omisson	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Exeltis Slovakia S.R.O.	Diecyclen	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Gedeon Richter Plc.	Mistra	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Genericon, S.R.O.	Paoletta	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Ladeepharma Slovakia, S.R.O.	Dienorette	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use

Member state EU/EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Slovakia	Sandoz Pharmaceuticals D.D.	Foxinette Neo	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovakia	Zentiva, K.S.	Zenadea	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovenia	Exeltis Magyarország Kft.	Dienille	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Slovenia	Gedeon Richter Plc.	Sibilla	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet \$ Lactose 37.26mg Tablet	Film-Coated Tablet	Oral use
Spain	Laboratorios Aurobindo S.L.U.	Dienogest/Etinilestradiol Aurobindo	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Spain	Laboratorios Cinfa, S.A.	Dienogest/Etinilestradiol Cinfa	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Ceciliana	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Ceciliana Diario	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use
Spain	Teva Pharma S.L.U	Verezana	Dienogest 2mg Tablet, Ethinylestradiol 0.03mg Tablet	Film-Coated Tablet	Oral use