



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Annexes 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 ulipristal acetate 5mg medicinal products

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

Procedure number: EMEA/H/A-31/1496

Esmya EMEA/H/A-31/1496/C/2041/0049

Ulipristal Acetate Gedeon Richter EMEA/H/A-31/1496/C/5017/0002

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Annexes A**List of centrally authorised medicinal products**

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Pack size
EU/1/12/750/001	Esmya	5 mg	Tablet	Oral use	blister (Alu/PVC/PE/PVDC)	28 tablets
EU/1/12/750/002	Esmya	5 mg	Tablet	Oral use	blister (Alu/PVC/PE/PVDC)	84 tablets
EU/1/12/750/003	Esmya	5 mg	Tablet	Oral use	blister (Alu/PVC/PE/PVDC)	30 tablets
EU/1/12/750/004	Esmya	5 mg	Tablet	Oral use	blister (Alu/PVC/PVDC)	28 tablets
EU/1/12/750/005	Esmya	5 mg	Tablet	Oral use	blister (Alu/PVC/PVDC)	84 tablets

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Pack size
EU/1/18/1309/001	Ulipristal Acetate Gedeon Richter	5 mg	Tablet	Oral use	blister (alu/PVC/PE/PVDC)	28 tablets
EU/1/18/1309/002	Ulipristal Acetate Gedeon Richter	5 mg	Tablet	Oral use	blister (alu/PVC/PE/PVDC)	84 tablets
EU/1/18/1309/003	Ulipristal Acetate Gedeon Richter	5 mg	Tablet	Oral use	blister (alu/PVC/PE/PVDC)	30 tablets
EU/1/18/1309/004	Ulipristal Acetate Gedeon Richter	5 mg	Tablet	Oral use	blister (alu/PVC/PVDC)	28 tablets
EU/1/18/1309/005	Ulipristal Acetate Gedeon Richter	5 mg	Tablet	Oral use	blister (alu/PVC/PVDC)	84 tablets

Annex I
List of nationally authorised medicinal products

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Croatia	Alvogen Pharma Trading Europe Eood	Ulipristalacetat Alvogen	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Czech Republic	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Czech Republic	Zentiva, K.S.	Stillupra	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
France	Accord Healthcare France Sas	Ulipristal Acetate Accord	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
France	Eg Labo Laboratoires Eurogenerics	Ulipristal Acetate Eg	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
France	Helm Ag	Ulipristal Acetate Helm	Ulipristal Acetate 5mg Tablet	Film-Coated Tablet	Oral Use
France	Zentiva France	Ulipristal Acetate Zentiva	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Accord Healthcare B.V.	Ulipristal Accord	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Aliud Pharma Gmbh	Ulipristal Al	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Cipla Europe Nv	Ulipristal Cipla	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Cyndea Pharma S.L	Ulipristal Cyndea	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Ulipristal Heumann	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Germany	Zentiva Pharma Gmbh	Ulipristal Zentiva	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Greece	Faran S.A.	Boled	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Hungary	Alvogen Pharma Trading Europe Eood	Ulipristál-Acetát Alvogen	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Hungary	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Iceland	Alvogen Pharma Trading Europe Eood	Ulipristal Asetat Alvogen	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Malta	G.L. Pharma Gmbh	Ulipristal G.L.	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Netherlands	Helm Ag	Ulipristal Helm	Ulipristal Acetate 5mg Tablet	Film-Coated Tablet	Oral Use
Netherlands	Sandoz B.V.	Elyoma	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Poland	Alvogen Pharma Trading Europe Eood	Ulipristal Alvogen	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Poland	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Ciclum Farma Unipessoal Lda.	Ulipristal Ciclum	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	G.L. Pharma Gmbh	Ulipristal G.L.	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Karevonal	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Selavona	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Portugal	Sumar Pharma Ehf	Ulipristal Sumar	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Varinam	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Zentiva Portugal, Lda	Stillupra	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Portugal	Zentiva Portugal, Lda	Ulipristal Zentiva	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Slovakia	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Slovakia	Zentiva, K.S.	Stillupra	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Spain	Adamed Laboratorios, S.L.U.	Missitel	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Spain	Cipla Europe Nv	Ulipristal Cipla	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Spain	Cyndea Pharma S.L	Ulipristal Cyndea	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
Spain	Helm Ag	Ulipristal Acetate Helm	Ulipristal Acetate 5mg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Accord Healthcare Limited	Ulipristal Acetate Accord Healthcare	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
United Kingdom	Cipla (Eu) Limited	Ulipristal Acetate Cipla	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
United Kingdom	Creo Pharma Ltd	Ulipristal Acetate Creo Pharma	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
United Kingdom	Helm Ag	Ulipristal Helm	Ulipristal Acetate 5mg Tablet	Film-Coated Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
United Kingdom	Mercury Pharmaceuticals Ltd.	Ulipristal Acetate Mercury Pharmaceuticals	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use
United Kingdom	Zentiva Pharma Uk Limited	Ulipristal Acetate Zentiva	Ulipristal Acetate 5mg Tablet	Tablet	Oral Use

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