

## **Annex I**

### **List of nationally authorised medicinal products**

## Annex IA – Lutinus and associated names

<b>Member State in EU/EEA</b>	<b>Product name</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Bulgaria	Lutinus	Ferring Arzneimittel Gmbh	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Czech Republic	Lutinus	Ferring-Léčiva, a.s.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Denmark	Lutinus	Ferring Lægemedler A/S	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Finland	Lutinus	Ferring Lääkkeet Oy	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Germany	Lutinus	Ferring Arzneimittel Gmbh	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Greece	Lutinus	Ferring Hellas Mepe	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Hungary	Lutinus	Ferring Magyarország Gyógyszerkereskedelmi Kft.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Iceland	Lutinus	Ferring Lægemedler A/S	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Ireland	Lutinus	Ferring Ireland Ltd.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Netherlands	Lutinus	Ferring B.V.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Norway	Lutinus	Ferring Legemidler As	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Poland	Lutinus	Ferring Gmbh	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE

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Portugal	Luferti	Ferring Portuguesa – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Romania	Lutinus	Ferring GmbH	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Slovakia	Lutinus	Ferring Léčiva A.S.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Slovenia	Lutinus	Ferring GmbH	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Spain	Lutinus	Ferring S.A.U.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
Sweden	Lutinus	Ferring Läkemedel Ab	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE
United Kingdom	Lutigest	Ferring Pharmaceuticals Ltd.	Progesterone	PROGESTERONE 100MG TABLET	VAGINAL TABLET	VAGINAL USE

## Annex IB – Dutasteride Actavis and associated names

Member State in EU/EEA	Product name	Marketing authorisation holder	INN	Strength	Pharmaceutical form	Route of administration
Austria	Dutasterid Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Bulgaria	Caminard	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Croatia	Caminard	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Czech Republic	Dutasterid Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Denmark	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Estonia	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Iceland	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Ireland	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Latvia	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Lithuania	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Norway	Dutasteride Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Poland	Dudactiv	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
Romania	Dutasteridă Actavis	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE

<b>Member State in EU/EEA</b>	<b>Product name</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Slovenia	Dutelas	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE
United Kingdom	Dutasteride Actavis Group	Actavis Group Ptc Ehf.	Dutasteride	DUTASTERIDE 0.5MG CAPSULE	CAPSULE, SOFT	ORAL USE

Annex IC – SoliCol D3

<b>Member State in EU/EEA</b>	<b>Product name</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
United Kingdom	SoliCol D3	Pharmaceutics (UK) Limited	Colecalciferol	COLECALCIFEROL 50,000 IU	TABLET	ORAL USE
United Kingdom	SoliCol D3	Pharmaceutics (UK) Limited	Colecalciferol	COLECALCIFEROL 20,000 IU	TABLET	ORAL USE