



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

## Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for estradiol-containing (0.01%w/w) medicinal products for topical use

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

Procedure number: EMEA/H/A-31/1482

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

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Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Pharmazeutische Fabrik Montavit Ges.M.B.H	Montadiol	Estradiol Hemihydrate 0.1033mgg	Cream	Vaginal Use
Austria	Pharmazeutische Fabrik Montavit Ges.M.B.H	Linoladiol	Estradiol Hemihydrate 0.1033mgg	Vaginal Emulsion	Vaginal Use
Bulgaria	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Линоладиол N	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Croatia	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol	Estradiol Hemihydrate 0.01033g	Vaginal Cream	Vaginal Use
Czech Republic	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Estonia	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Germany	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Estradiol-Hemihydrat Wolff	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Germany	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Hungary	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol	Estradiol Hemihydrate 0.01033g/100g	Vaginal Cream	Vaginal Use
Latvia	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033g	Vaginal Cream	Vaginal Use
Lithuania	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033gg	Vaginal Cream	Vaginal Use
Slovakia	Dr. August Wolff Gmbh & Co. Kg Arzneimittel	Linoladiol N	Estradiol Hemihydrate 0.01033g	Vaginal Cream	Vaginal Use