

Summary Public Assessment Report

Generics

**Estradiol Valeraat 1 mg/Dienogest 2 mg
Laboratorios León Farma, film-coated tablets**

(estradiol valerate and dienogest)

NL/H/2949/002/DC

Date: 11 December 2014

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Generics

Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma, film-coated tablets
Active substances: estradiol valerate and dienogest

This is a summary of the public assessment report (PAR) for Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma, film-coated tablets. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma and what is it used for?

Estradiol Valeraat/Dienogest Laboratorios León Farma is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Climodien 1 mg/2 mg coated tablets.

This medicine is used for relief of symptoms occurring after menopause. It is only prescribed in women with at least 12 months since their last natural period, if the symptoms seriously hinder a woman's daily life.

How does this medicine work?

During the menopause, the amount of oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). This medicine is a Hormone Replacement Therapy (HRT). It contains two types of female hormones, an oestrogen and a progestogen, and alleviates the symptoms after menopause.

How is this medicine used?

The pharmaceutical form of Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?

Because this is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Climodien. Two medicines are bioequivalent when they produce the same levels of the active substances in the body.

What are the possible side effects of this medicine?

Because Estradiol Valeraat/Dienogest Laboratorios León Farma is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?

It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Climodien 1 mg/2 mg, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?

A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine

In the Netherlands, the marketing authorisation for Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma film-coated tablets was granted on 26 September 2014.

The full PAR for this medicine can be found on the website <http://mri.medagencies.org/Human>. For more information about treatment with Estradiol Valeraat 1 mg/Dienogest 2 mg Laboratorios León Farma, read the package leaflet (http://mri.medagencies.org/download/NL_H_2949_002_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in December 2014.