

Summary Public Assessment Report

Dienogest León Farma (dienogest)

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(dienogest)

Tablet, 2 mg

This is a summary of the public assessment report (PAR) for Dienogest León Farma. It explains how Dienogest León Farma 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 Dienogest León Farma.

For practical information about using Dienogest León Farma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dienogest León Farma and what is it used for?

Dienogest León Farma is a ‘generic medicine’. This means that Dienogest León Farma is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Visanne.

Dienogest León Farma is a preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).

How does Dienogest León Farma work?

Dienogest León Farma contains a hormone, the progestogen dienogest. It works by suppressing oestradiol production and preventing the growth of the endometrium.

How is Dienogest León Farma used?

The pharmaceutical form of Dienogest León Farma is tablets for oral use.

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

The medicine can only be obtained with a prescription.

What benefits of Dienogest León Farma have been shown in studies?

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

What are the possible side effects of Dienogest León Farma?

Because Dienogest 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 restrictions, see the package leaflet.

Why is Dienogest León Farma approved?

It was concluded that, in accordance with EU requirements, Dienogest León Farma has been shown to have comparable quality and to be bioequivalent to the reference medicine Visanne. Therefore, the Medical Products Agency in Sweden decided that, as for Visanne, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Dienogest León Farma?

A risk management plan has been developed to ensure that Dienogest León Farma 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 Dienogest 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 Dienogest León Farma

The marketing authorisation for Dienogest León Farma was granted on 2019-06-07 in Sweden.

The full PAR for Dienogest León Farma can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Dienogest León Farma, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-06.