LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Endovelle
(dienogest)

SE/H/1787/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Endovelle
(dienogest)

Tablet, 2 mg

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

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

What is Endovelle and what is it used for?

Endovelle is a 'generic medicine'. This means that Endovelle is similar to a 'reference medicine' already authorised in the European Union (EU) called Visanne.
Endovelle is a preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).

How does Endovelle work?

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

How is Endovelle used?

The pharmaceutical form of Endovelle 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 Endovelle have been shown in studies?

Because Endovelle 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 Endovelle?

Because Endovelle 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 Endovelle approved?

It was concluded that, in accordance with EU requirements, Endovelle 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 Endovelle?

A risk management plan has been developed to ensure that Endovelle 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 Endovelle, 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 Endovelle

The marketing authorisation for Endovelle was granted on 2019-02-26 in Sweden.

The full PAR for Endovelle can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Endovelle, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2019-06.