LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vinelle
(desogestrel)

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(desogestrel)

Tablets; 75 micrograms

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

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

What is Vinelle and what is it used for?
Vinelle is a 'generic medicine'. This means that Vinelle is similar to a 'reference medicine' already authorised in the European Union (EU) called Cerazette.

Vinelle is used to prevent pregnancy. Vinelle contains a small amount of one type of female sex hormone, the progestogen desogestrel.
For this reason Vinelle is called a progestogen-only-pill (POP), or a mini-pill. Contrary to the combined pill, the POP or mini-pill does not contain an oestrogen hormone next to the progestogen.

How does Vinelle work?
Most POPs or minipills work primarily by preventing the sperm cells from entering the womb but they do not always prevent the egg cell from ripening, which is a difference from the combined pills.
Vinelle is distinct from other mini-pills in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Vinelle provides high efficacy in prevention of pregnancies.

How is Vinelle used?
The pharmaceutical form of Vinelle 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 Vinelle have been shown in studies?
Because Vinelle is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Cerazette. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Vinelle?
Because Vinelle 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 Vinelle approved?
It was concluded that, in accordance with EU requirements, Vinelle has been shown to have comparable quality and to be bioequivalent to the reference medicine Cerazette. Therefore, the Medical Products Agency in Sweden decided that, as for Cerazette, 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 Vinelle?
A risk management plan has been developed to ensure that Vinelle 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 Vinelle, 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 Vinelle
The marketing authorisation for Vinelle was granted on 2014-11-13 in Sweden.

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

This summary was last updated in 2014-11-13.