LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Qleyla
(estradiol valerate, dienogest)

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estradiol valerate, dienogest

Film-coated tablet

This is a summary of the public assessment report (PAR) for Qleyla. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Qleyla and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Qlaira.

The product is a contraceptive used to prevent pregnancy.

How does Qleyla work?

Estradiol valerate and dienogest mediate their effect by interacting with estrogen and progesterone receptors causing an ovulatory inhibition. The contraceptive effect of combined oral contraceptives is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation, changes in the cervical secretion, and changes in the endometrium.

How is Qleyla used?
The pharmaceutical form is film-coated tablet 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 in Sweden.

What benefits of Qleyla have been shown in studies?

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

What are the possible side effects from Qleyla?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Qleyla approved?

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

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Qleyla?”

What measures are being taken to ensure the safe and effective use of Qleyla?
A risk management plan has been developed to ensure that the product 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, 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.

To encourage safe prescribing of combined hormone contraceptives (CHCs), to inform about extent and characteristics of VTE and ATE risk with CHCs and to promote early diagnosis, treatment, and prevention of complications from VTE and ATE, education material to prescribers and patients should be provided. For more details, please see the full PAR for Qleyla on the following website: MRI - Home.

Other information about Qleyla
The full PAR for Qleyla can be found on the following website: MRI - Home. For more information about treatment with Qleyla, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-03.