

Summary Public Assessment Report

Estradiol SUN (estradiol hemihydrate)

SE/H/2050/01/DC

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estradiol hemihydrate

Vaginal tablet, 10 microgram

This is a summary of the public assessment report (PAR) for Estradiol SUN. 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 Estradiol SUN and what is it used for?

The product is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

The product is used to relieve menopausal symptoms in the vagina such as dryness or irritation. In medical terms this is known as ‘vaginal atrophy’. It is caused by a drop in the levels of oestrogen in the body. This happens naturally after the menopause.

How does Estradiol SUN work?

Estradiol SUN works by replacing the oestrogen which is normally produced in the ovaries of women. It is inserted into the vagina, so the hormone is released where it is needed. This may relieve discomfort in the vagina.

How is Estradiol SUN used?

The pharmaceutical form is vaginal tablet for vaginal insertion.

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 Estradiol SUN have been shown in studies?

As estradiol is a well-known substance, and its use in the treatment of vaginal atrophy is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of estradiol in the treatment of the above-mentioned indication.

What are the possible side effects from Estradiol SUN?

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 Estradiol SUN approved?

The Swedish Medical Products Agency decided that 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 Estradiol SUN?

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.

Other information about Estradiol SUN

The full PAR for Estradiol SUN can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Estradiol SUN, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-10.