LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vagidonna
estradiol hemihydrate, estradiol

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Vaginal tablet, 10 mikrogram

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

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

What is Vagidonna and what is it used for?

Vagidonna is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Vagidonna is Vagifem. Vagidonna is used to relieve 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 your body. This happens naturally after the last regular menstruation period (menopause).

Vagidonna belongs to a group of medicines called vaginal Hormone Replacement Therapy (HRT).

How does Vagidonna work?

Vagidonna contains estradiol. Estradiol is a female sex hormone. It belongs to a group of hormones called oestrogens. It is exactly the same as the estradiol produced by the ovaries of women. Vagidonna works by replacing the oestrogen which is normally produced in the ovaries of women. It is inserted into your vagina, so the hormone is released where it is needed. This may relieve discomfort in the vagina.

How is Vagidonna used?

The pharmaceutical form of Vagidonna is a vaginal tablet for vaginal administration.

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 be obtained without a prescription in Sweden.

What benefits of Vagidonna have been shown in studies?

Because Vagidonna is a hybrid application and is considered to be therapeutically equivalent, to the reference product Vagifem, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Vagidonna?

For the full list of all side effects reported with Vagidonna, see section 4 of the package leaflet.

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

Why is Vagidonna approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Vagidonna's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Vagidonna?

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

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

This summary was last updated in 2020-04.