LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Utrogestan
(progesterone)

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progesterone

vaginal capsule, soft, 300 mg

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

Utrogestan can be used to support pregnancy during fertility treatment techniques using the patient´s own eggs, such as in-vitro fertilization (IVF).
Utrogestan is also used in the treatment of patients who need extra hormone (progesterone) while undergoing fertility treatment in an Assisted Reproductive Technology (ART) program.

Utrogestan is not a contraceptive.

How does Utrogestan work?

Utrogestan contains a female sex hormone called progesterone. Progesterone is produced in the monthly formed “corpus luteum” of the ovaries as well as in the placenta. Utrogestan has all the properties of the body´s naturally produced progesterone. It acts on the uterus by converting its growth phase into secretory phase during the menstrual cycle.

How is Utrogestan used?

The pharmaceutical form is capsule, soft for vaginal 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 Utrogestan have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating adult women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.

What are the possible side effects from Utrogestan?

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 Utrogestan 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 Utrogestan?

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 Utrogestan

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

This summary was last updated in 2023-05.