LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Utrogestan
(progesterone)

SE/H/2023/02/DC

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progesterone

Vaginal capsule, soft, 400 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?
The product contains a hormone called progesterone and can be used to reduce the risk of miscarriage in women with bleeding in the current pregnancy and a history of recurrent miscarriages.

How does Utrogestan work?
Progesterone modulates maternal immune responses to protect the foetus, improves the blood flow of the uterus and placenta, maintains cervical integrity throughout pregnancy, promotes relaxation of the muscles of the uterus, and possesses anti-inflammatory properties.

How is Utrogestan used?
The pharmaceutical form is vaginal 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 reducing the risk of miscarriage in women with bleeding in the current pregnancy and a history of recurrent miscarriages.

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 2023-11.