

PACKAGE LEAFLET: INFORMATION FOR THE
USER

Utrogestan Vaginal 200 mg Vaginal Capsules, soft progesterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Utrogestan Vaginal is and what it is used for
2. What you need to know before you use Utrogestan Vaginal
3. How to use Utrogestan Vaginal
4. Possible side effects
5. How to store Utrogestan Vaginal
6. Contents of the pack and other information

1. What Utrogestan Vaginal is and what it is used for

The name of your medicine is Utrogestan Vaginal 200 mg Vaginal Capsules, soft. Utrogestan Vaginal contains a hormone called progesterone.

What Utrogestan Vaginal is used for

To support pregnancy during fertility treatment

Utrogestan Vaginal is for women who need extra progesterone to support pregnancy while undergoing treatment in an Assisted Reproductive Technology (ART) programme.

To prevent premature birth in women with a singleton pregnancy

Utrogestan Vaginal is for women who have previously had a premature baby and/or who may have a problem with part of their womb, known as a short cervix.

2. What you need to know before you use Utrogestan Vaginal

Do not use Utrogestan Vaginal:

- **If you are allergic (hypersensitive) to soya or peanuts**
- If you are allergic to progesterone or any of the other ingredients of this medicine (listed in Section 6)
- If you have liver problems
- If you have yellowing of the skin or eyes (jaundice)
- If you have unexplained vaginal bleeding

- If you have mammary or genital tract carcinoma
- If you have thrombophlebitis
- If you have or have had blood clots in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have had a cerebral haemorrhage
- If you have a rare blood problem called “porphyria” which is passed down in families (inherited)
- If you are pregnant but your baby has died inside of you (missed abortion)
- If your “waters break”.

Do not use Utrogestan Vaginal if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Utrogestan Vaginal.

Warning and precautions

Utrogestan Vaginal is not a contraceptive.

If you think you may have miscarried, you should speak to your doctor as you must stop using Utrogestan Vaginal.

If you have vaginal bleeding speak to your doctor.

If you are taking this medicine to support pregnancy during fertility treatment

Utrogestan Vaginal should only be used during the first 3 months of pregnancy.

If you are taking this medicine to prevent preterm birth in women with a singleton pregnancy

Your doctor should discuss the risks and benefits of the options available to you. You and your doctor should make a shared decision on which treatment is most suitable.

If you are at risk of having your baby prematurely, you may be given Utrogestan Vaginal from around week 20 to week 34 of your pregnancy. If your waters break while you are taking the medicine, you must see your doctor as soon as possible. If this happens there may be an immediate risk to you and your baby.

In rare cases, use during the second and third trimester of pregnancy may lead to the development of liver problems. Contact your doctor if you experience itching which may be a sign of liver problems.

Children

Utrogestan Vaginal is not for use in children.

Tests and Check-ups

Your doctor will perform a complete medical examination before starting the treatment and regularly during the treatment.

Other medicines and Utrogestan Vaginal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Utrogestan Vaginal can affect the way some other medicines work. Also some other medicines can affect the way Utrogestan Vaginal works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Bromocriptine used for problems with the pituitary gland or Parkinson's Disease.
- Ciclosporin (used to suppress the immune system).
- Rifamycin medicines such as rifampicin (used to treat infections).
- Ketoconazole (used for fungal infections).

Utrogestan Vaginal with food and drink

Utrogestan Vaginal should be inserted into the vagina. Food and drink do not affect the treatment.

Pregnancy, breast-feeding and fertility

- Utrogestan Vaginal will help support pregnancy if you are having fertility treatment or if your doctor has told you that you are at risk of having your baby prematurely. For instructions on how to use Utrogestan Vaginal, see Section 3.
- Do not use Utrogestan Vaginal if you are breast-feeding.

Driving and using machines

Utrogestan Vaginal has negligible effects on driving or using machinery.

Utrogestan Vaginal contains soybean lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use Utrogestan Vaginal

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Use this medicine by inserting it deep into the vagina.
- Do not take it by mouth. If you accidentally take Utrogestan Vaginal by mouth, it will not harm you, but your chances of becoming pregnant will be reduced.

Recommended dose

For support during in vitro fertilization (IVF) cycles:

- The treatment is started no later than the third day after egg retrieval.
- Every day, use 600 mg of Utrogestan Vaginal as instructed by the doctor. Insert one capsule deep into the vagina in the morning, at midday and at bedtime.
- If laboratory tests confirm that you are pregnant, continue with the same dose until at least the 7th week of pregnancy but no longer than the 12th week of pregnancy, according to your doctor's instructions.

For prevention of premature birth in certain women:

- Every day, use 200 mg of Utrogestan Vaginal in the evening at bedtime from around week 20 to week 34 of pregnancy.

If you use more Utrogestan Vaginal than you should

If you use too much Utrogestan Vaginal, you should talk to your doctor or go to a

hospital. Take the medicine pack with you.

The following effects may happen: feeling dizzy or feeling tired.

If you forget to use Utrogestan Vaginal

- If you forget a dose, insert it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you stop using Utrogestan Vaginal

Talk to your doctor, pharmacist or nurse before stopping to use this medicine. If you stop using the medicine, it will not help you to get pregnant.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Frequency not known (frequency cannot be estimated from the available data):

- itching
- oily discharge from the vagina
- vaginal haemorrhage
- burning sensation

Short-term tiredness or dizziness may be experienced within 1 – 3 hours after taking the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Utrogestan Vaginal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the packaging after Exp. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use this medicine if you notice visible changes in the appearance of the medicine.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Utrogestan Vaginal contains

- The active substance is progesterone. Each capsule contains 200mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin. The other ingredients in the capsule shell are gelatin, glycerol, titanium dioxide (E171) and water, purified.

What Utrogestan Vaginal looks like and contents of the pack

- Utrogestan Vaginal are oval and slightly yellow soft capsules, containing whitish oily suspension.
- They are supplied in cartons containing PVC/Aluminium blisters of 15, 21, 45 or 90 capsules

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Utrogestan Vaginal is held by:
Besins Healthcare Ireland Limited
16 Pembroke Street Upper
Dublin 2
D02HE63
Ireland

Utrogestan Vaginal is manufactured by:

Cyndeia Pharma, S.L.
Polígono Industrial Emiliano Revilla Sanz,
Avenida de Agreda, 31,
Ólvega 42110 (Soria),
Spain.

Or

BESINS MANUFACTURING ESPAÑA
Polígono Industrial El Pitarco, parcela nr. 4
50450 Muel (Zaragoza)
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria: Utrogestan 200 mg vaginal capsules, soft
Croatia: Utrogestan 200 mg meke kapsule za rodnicu.
Czech Republic: Progesteron Besins 200 mg měkké tobolky
Denmark: Progestan
Estonia: Utrogestan 200 mg vaginaalpehmekapslid
Hungary: Utrogestan 200 mg lágy hüvelykapszula
Iceland: Progestan 200 mg Mjúkt skeiðarhylki
Ireland: Utrogestan Vaginal 200 mg Vaginal Capsules, soft
Italy: Utrogestan Vaginale 200 mg Capsula molle
Latvia: Progesterone Besins 200 mg vaginālās mīkstās kapsulas
Lithuania: Progesterone Besins 200 mg makšties minkštosios kapsulės
Malta: Utrogestan Vaginal 200 mg Capsules, soft
Netherlands: Utrogestan 200 mg, zachte capsules voor vaginaal gebruik
Norway: Utrogestan 200 mg vaginalkapsler, myke
Poland: Utrogestan 200 mg, kapsułki dopochwowe, miękkie

Portugal: Utrogestan Vaginal 200 mg Cápsula mole
Slovakia: Utrogestan 200 mg, mäkké vaginálne kapsuly
Slovenia: Utrogestan 200 mg mehke vaginalne kapsule
Spain: Utrogestan Vaginal 200 mg Cápsula blanda
Sweden: Utrogestan 200 mg mjuk Vaginalkapsel
United Kingdom: Utrogestan Vaginal 200 mg Capsules

This leaflet was last revised in November 2023