

Package leaflet: Information for the user
Utrogestan Vaginal 300 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 further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. 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 300 mg Vaginal Capsules, soft (called Utrogestan Vaginal in this leaflet). Utrogestan Vaginal contains a hormone called progesterone.

What Utrogestan Vaginal is used for

Utrogestan Vaginal can be used to support pregnancy during in vitro fertilization (IVF) cycles.

To support pregnancy

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

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 breast cancer or genital tract carcinoma
- if you have thrombophlebitis
- if you have or have had blood clots in a vein (thrombosis), such as in the leg (deep vein thrombosis) or the lungs (pulmonary embolism)
- if you have had a cerebral haemorrhage or stroke
- if you have a rare blood disease called porphyria, which is passed down in families (inherited)
- if you are pregnant but your baby has died inside of you (missed abortion).

Warnings and precautions

Utrogestan Vaginal should only be used during the first 3 months of pregnancy. Talk to your doctor or pharmacist before using Utrogestan Vaginal.

Utrogestan Vaginal is not a contraceptive.

If you have diabetes and use insulin to control your blood sugar levels, progesterone treatment may affect your response to insulin and your antidiabetics' medication might need adjustment.

If you have vaginal bleeding speak to your doctor.

If you believe that you have had a miscarriage, you must speak with your doctor, because you must stop using Utrogestan Vaginal.

You must contact your doctor if you feel unwell within a few days of taking the medicine.

Children and adolescents

Utrogestan Vaginal is not for use in children and adolescents.

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:

- blood thinners such as coumarins or phenindione
- ciclosporin or tacrolimus (used to reduce the immune response)
- tizanidine (muscle relaxant)
- bromocriptine, which is used in the treatment of pituitary gland-related problems or Parkinson's disease
- selegiline (for treating Parkinson's disease)
- diazepam, chlordiazepoxide, alprazolam, oxazepam or lorazepam (for treating anxiety or insomnia)
- tuberculosis medicines (such as rifampicin and rifabutin)
- antibiotics (for example griseofulvin, ampicillin, amoxicillin and tetracyclines), which are used to treat certain infections
- phenytoin, phenobarbital, carbamazepine, eslicarbazepine, oxcarbazepine, primidone/rufinamide, perampanel or topiramate (used for epilepsy)
- herbal medicine products, containing St John's Wort
- darunavir, nelfinavir, fosamprenavir or lopinavir (used to treat viral infections)
- bosentan (used to treat lung problems)
- fluconazole, itraconazole, voriconazole (for the treatment of fungal infections)
- ketoconazole (used to treat Cushing's syndrome – when the body produces and excess of cortisol)
- atorvastatin or rosuvastatin (used to control cholesterol)
- aprepitant (used to prevent nausea and vomiting).

If you have recently been given an anaesthetic, such as bupivacaine or

If you have been recently been tested for liver or hormone problems.

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 support pregnancy if you are having fertility treatment. For instructions on how to use Utrogestan Vaginal see Section 3 on how to use Utrogestan Vaginal.
- Do not use Utrogestan Vaginal if you are breast-feeding.

Driving and using machines

Utrogestan Vaginal has no or 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.

Using this medicine is to assist in getting pregnant

- 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

- 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 and the other at bedtime.
- If laboratory tests confirm that you are pregnant, continue with same dose until at least the 7th week of pregnancy and not later than the 12th week of pregnancy according to your doctor's instructions.

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 your 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:

Very rare (may affect up to 1 in 10,000 people):

- Serious allergic reaction which causes difficulty in breathing or dizziness

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

- Itching
- Vaginal bleeding
- Oily discharge from the vagina.

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

If you notice side effects other than those mentioned above, tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 which is stated on the packaging after EXP. The expiry date refers to the last day of that month.
- Once the bottle has been opened, use the capsules within 15 days.
- Store in the original packaging (the bottle).
- Store below 30°C.
- 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. One capsule contains 300mg of progesterone.
- The other ingredients in the capsule are refined sunflower oil, soyabean lecithin, gelatine, glycerol (E422), titanium dioxide (E171) and purified water.

What Utrogestan Vaginal looks like and contents of the pack

The capsules are oblong yellowish, soft gelatin capsules, that contain a whitish oily suspension. The dimensions of the 300 mg capsule are approximately 2.5 cm x 0.8 cm.

Utrogestan Vaginal are supplied in white high density polyethylene plastic bottles with a child resistant white polypropylene screw cap and a tearable silver coloured seal. Pack size: 1 bottle containing 15 capsules.

Marketing Authorisation Holder

The Marketing Authorisation for Utrogestan Vaginal is held by :

Besins Healthcare Ireland Limited
16 Pembroke Street Upper
Dublin 2
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Ireland

Manufacturer

Cyndeia Pharma S.L.
Poligono Industrial Emiliano Revilla Sanz
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This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria, Estonia, Hungary, Croatia, Cyprus, France, Italy, Malta, The Netherlands, Norway, Poland, Portugal Sweden, Slovenia, Slovakia, Spain: Utrogestan

Belgium, Ireland, Luxembourg: Utrogestan Vaginal

Finland: Lugesteron

Latvia, Lithuania: Progesterone Besins

Denmark, Iceland: Progestan

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