

**Package leaflet: Information for the user**

**Utrogestan 300 mg vaginal capsule, 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, 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 <invented name> is and what it is used for
2. What you need to know before you use <invented name>
3. How to use <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

**1. What <invented name> is and what it is used for**

The name of your medicine is <invented name>. <invented name> contains a hormone called progesterone.

**What <invented name> is used for**

<invented name> can be used to support pregnancy during in vitro fertilization (IVF) cycles.

**To support pregnancy**

<invented name> 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 <invented name>**

**Do not use <invented name>**

- if you are allergic to progesterone, soya, peanut 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**

<invented name> should only be used during the first 3 months of pregnancy. Talk to your doctor or pharmacist before using <invented name>

<invented name> 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 <invented name>.

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

### **Children and adolescents**

<invented name> is not indicated for use in children and adolescents

### **Other medicines and <invented name>**

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 <invented name> can affect the way some other medicines work. Also some other medicines can affect the way <invented name> works.

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

- Medicine used to help you relax or sleep (phenobarbital, pentobarbital)
- Medicine to control seizure/epilepsy (e.g. phenytoin or carbamazepine)
- Medicine used to treat tuberculosis in particular rifampicin
- Herbal remedies for low mood or anxiety containing St John's wort
- Medicine used to treat fungal infections (e.g. ketoconazole)
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### **<invented name> with food and drink**

<invented name> should be inserted into the vagina. Food and drink do not affect the treatment.

### **Pregnancy, breast-feeding and fertility**

- <invented name> will support pregnancy if you are having fertility treatment. For instructions on how to use <invented name>, see Section 3.
- Do not use <invented name> if you are breast-feeding.

## **Driving and using machines**

<Invented name> is not expected to affect your ability to drive or use machines. However, in some people it may cause dizziness and tiredness. If these effects occur, caution is advised in drivers and users of machines

<invented name> **contains soybean lecithin**

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

<Invented name> contains highly refined sunflower oil, which very rarely causes a reaction in adults allergic to refined oils.

## **3. How to use <invented name>**

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 <invented name> 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 <invented name> 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 7<sup>th</sup> week of pregnancy and not later than the 12<sup>th</sup> week of pregnancy according to your doctor's instructions.

### **If you use more <invented name> than you should**

If you use too much <invented name> 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.

Applicable for FI only: If you have taken too large a dose or if a child has taken this medicine by mistake, contact a doctor, hospital or the Poison Information Centre (tel <xxx>) for assessment of the risk and further advice.

### **If you forget to use <invented name>**

- 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 <invented name>**

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
- dizziness
- feeling very tired (fatigue)
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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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store <invented name>**

- 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 carton and bottle label 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.
- 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 protect the environment.

## **6. Contents of the pack and other information**

### **What <invented name> contains**

- The active substance is progesterone. Each soft vaginal capsule contains 300mg progesterone.
- The other ingredients in the capsule are refined sunflower oil, soyabean lecithin (E322), gelatin (E441), glycerol (E422), titanium dioxide (E171) and purified water.

### **What <invented name> looks like and contents of the pack**

The capsules are oblong yellowish, (approximately 2.5 cm x 0.8 cm) soft vaginal capsules, containing a whitish oily suspension. .

<invented name> is available in a bottle containing 15 soft vaginal capsules.

or

- PVC/Aluminium blisters of 15, 30 or 45 capsules.

Not all pack sizes may be marketed

**The Marketing Authorisation Holder for <invented name> is held by**

<[To be completed nationally]>

**Manufacturer**

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

Or

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

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

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

Belgium, Ireland, Luxembourg: Utrogestan Vaginal

Finland, Spain: Lugesteron

Latvia, Lithuania: Progesterone Besins

Czech Republic: Progesteron Besins

Denmark, Iceland: Progestan

**This leaflet was last revised on**

**2026-02-04**

**Other sources of information**

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}