

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Utrogestan 200 mg soft vaginal capsules 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 <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**

##### **To support pregnancy during fertility treatment**

<invented name> is for women who need extra progesterone to support pregnancy while undergoing treatment in an Assisted Reproductive Technology (ART) program.

##### **To prevent premature birth in women with a singleton pregnancy**

<invented name> is for women who have previously had a premature baby and/or who have a short cervix.

#### **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 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 <invented name> if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using <invented name>.

### **Warning and precautions**

<invented name> is not a contraceptive.

If you think you may have miscarried, you should speak to your doctor as you must stop using <invented name>.

If you have vaginal bleeding speak to your doctor.

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

<invented name> 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 <invented name> 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**

<invented name> 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 <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)

### **<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 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 <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.

- Use this medicine by inserting it deep into the vagina.
- 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**

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 <invented name> 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 7<sup>th</sup> week of pregnancy but no longer than the 12<sup>th</sup> week of pregnancy, according to your doctor's instructions.

For prevention of premature birth in certain women:

- Every day, insert one capsule (200 mg) of <invented name> deep into the vagina, in the evening at bedtime. This medicine may be given from around week 20 to week 34 of pregnancy.

### **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.

### **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 the 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
- feeling very tired (fatigue)
- dizziness

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 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 stated on the carton and blister 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 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 200mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin (E322). The other ingredients in the capsule shell are gelatin (E441), glycerol (E422), titanium dioxide (E171) and water, purified.

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

- <invented name> are oval yellowish soft vaginal capsules, containing a whitish oily suspension.
- <Invented name> are available in cartons containing PVC/Aluminium blisters of 15, 21, 45 or 90 capsules.

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

<[To be completed nationally]>

#### **Manufacturer**

Cyndeia Pharma, S.L.  
Polígono Industrial Emiliano Revilla Sanz  
Avenida de Ágreda, 31, Olvega  
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 European Economic Area and in the United Kingdom (Northern Ireland) 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 200mg 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  
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 200mg Capsules

**This leaflet was last revised in 2026-02-04**

#### **Other sources of information**

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