

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**UTROGESTAN® VAGINAL 200mg 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 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 200mg Capsules (called Utrogestan Vaginal in this leaflet). 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 or stroke
- 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 following 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 unexpected vaginal bleeding speak to your doctor.

**If you are taking this medicine as part of 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 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 (200mg) of Utrogestan Vaginal deep into the vagina, in the evening at bedtime. This medicine may be given from around week 20 to 34 of pregnancy.

### If you use more Utrogestan Vaginal than you should

If you use too much Utrogestan Vaginal, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store Utrogestan Vaginal

- **Keep 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.
- This medicine does not require any special storage conditions.
- If your medicine shows any signs of deterioration or discolouration, consult your doctor or pharmacist for advice. If damaged, please tell your doctor or pharmacist.

- 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 soft capsule contains 200mg of progesterone.
- The other ingredients are sunflower oil and soya lecithin. The other ingredients in the capsule shell are gelatin, glycerol, titanium dioxide (E171) and purified water.

#### What Utrogestan Vaginal looks like and contents of the pack

- Utrogestan Vaginal are oval and slightly yellow, soft capsules, containing white oily suspension.
- Each blister pack contains 7 capsules
- Each pack contains 21 capsules.

UTROGESTAN is a registered trademark.

Manufactured by: Cyndea Pharma, S.L., Poligono 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. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

PL 20774/2530 UTROGESTAN VAGINAL  
200mg Capsules

POM

This leaflet was revised 17<sup>th</sup> November 2025

Blind or partially sighted?  
Is this leaflet hard to see or read?  
Contact Quadrant Pharmaceuticals  
Ltd, Tel: 01204 471 269

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**PROGESTERONE VAGINAL 200mg Capsules**

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**What is in this leaflet:**

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2. What you need to know before you use Progesterone Vaginal
3. How to use Progesterone Vaginal
4. Possible side effects
5. How to store Progesterone Vaginal
6. Contents of the pack and other information

**1. What Progesterone Vaginal is and what it is used for**

The name of your medicine is PROGESTERONE VAGINAL 200mg Capsules (called Progesterone Vaginal in this leaflet).

Progesterone Vaginal contains a hormone called progesterone.

**What Progesterone Vaginal is used for**

**To support pregnancy during fertility treatment**

Progesterone 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**

Progesterone 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 Progesterone Vaginal**

**Do not use Progesterone 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
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- If you are pregnant but your baby has died inside of you (missed abortion)
- If your "waters break".

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

**Warning and precautions**

Progesterone Vaginal is not a contraceptive.

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

If you have unexpected vaginal bleeding speak to your doctor.

**If you are taking this medicine as part of fertility treatment**

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

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If you are at risk of having your baby prematurely, you may be given Progesterone 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.

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**Children**

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**Progesterone Vaginal with food and drink**

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**Pregnancy, breast-feeding and fertility**

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**Driving and using machines**

Progesterone Vaginal has negligible effects on driving or using machinery.

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**3. How to use Progesterone Vaginal**

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