

Package leaflet: information for the user

Utrogestan 200 mg, soft capsules for vaginal use  
progesterone

Read the entire 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.

Do you have any questions? Then contact your doctor, pharmacist, or nurse.

Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet:

1. What is Utrogestan 200 mg and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the package and other information

## 1. What is Utrogestan 200mg and what is it used for?

The name of this medicine is Utrogestan 200 mg, soft capsules for vaginal use (referred to in this leaflet as Utrogestan 200 mg or 'this medicine'). This medicine contains progesterone (a hormone).

When is Utrogestan 200 mg used

This medicine can be used to support pregnancy during fertility treatments (for women who have difficulty becoming pregnant) or to prevent preterm birth in certain women who are pregnant with one child.

Support during pregnancy in a fertility treatment

This medicine is for women who need extra progesterone to support pregnancy during fertility treatment.

Prevention of preterm birth in women with a singleton pregnancy Utrogestan is intended for the treatment of women who have previously had a premature baby and/or have a short cervix.

## 2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

If allergic (hypersensitive) to soy or peanuts

If you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you have liver problems.

If you experience yellowing of the skin or eyes (jaundice)

Vaginal bleeding without a known cause

In case of breast cancer or cancer of the reproductive organs;

If you have a blocked blood vessel due to a blood clot, and inflammation in the blood vessel wall (thrombophlebitis)

If you have or have had blood clots in a blood vessel (thrombosis), for example in the legs (deep vein thrombosis) or the lungs (pulmonary embolism)

If you have had a stroke.

If you have a rare hereditary enzyme disorder with symptoms including skin manifestations (porphyria)

If you are pregnant with a lifeless (dead) baby (missed miscarriage)

If your membranes rupture

Do not use Utrogestan if any of the above apply to you. If you have questions, contact your doctor or pharmacist before using Utrogestan.

When should you be extra careful with this medicine?

This medicine is not a means to prevent pregnancy (contraceptive). If you think you have a miscarriage, contact your doctor because you should no longer use this medicine.

If you have vaginal bleeding, contact your doctor.

If you are using this medicine to support a pregnancy during fertility treatment

This medicine should only be used during the first 3 months of pregnancy.

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

Your doctor should discuss the risks and benefits of the available options with you. You and your doctor should decide together which treatment is most suitable.

If there is a risk that your baby will be born prematurely, you can receive this medicine from about week 20 to week 34 of your pregnancy. If your waters break while using the medicine, you should go to 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 can lead to liver problems. Contact your doctor if you experience itching, which may be a sign of liver problems.

Children

This medicine is not suitable for use in children.

Testing and monitoring

Your doctor will conduct a complete medical examination before starting treatment with this medicine and also at regular intervals during the treatment.

Are you using any other medicines?

Are you using any other medicines besides Utrogestan 200 mg, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines you can buy without a prescription and

herbal medicines. Utrogestan 200 mg can affect how other medicines work, and other medicines can affect how Utrogestan 200 mg works.

Inform your doctor or pharmacist in any case if you are using any of the following medicines:

Bromocriptine (used for problems with the pituitary gland (a gland in the brain that produces hormones) or Parkinson's disease)

Ciclosporin (used to suppress the immune system)

Rifamycins such as rifampicin (for the treatment of infections)

Ketoconazole (for the treatment of fungal infections)

What should you pay attention to with food and drink?

This medicine should be administered via the vagina. Food and drink will not affect the treatment.

Pregnancy, breastfeeding, and fertility

This medicine helps you to become pregnant when you are undergoing fertility treatment or if your doctor has told you that you have a risk of early miscarriage. For instructions on how to use this medicine, see section 3.

Do not use this medicine if you are breastfeeding.

Driving and using machines

This medicine has almost no (a negligible) effect on the ability to drive and use machines.

Utrogestan 200 mg contains soy lecithin

Do not use this medicine if you are allergic to peanuts and soy.

3. How to use this medicine?

Follow the instructions of your treating doctor or pharmacist carefully. Contact your doctor or pharmacist if you are unsure about the use.

Insert this medicine deep into the vagina.

Do not swallow the medicine. If you accidentally swallow this medicine, it will not have a harmful effect on you. However, it will reduce the chance of pregnancy.

Recommended dosage

For support of pregnancy during fertility treatment (IVF):

Your treatment starts no later than the third day after harvesting the eggs.

Use 600 mg of this medicine every day in the manner as told by your doctor. Insert 1 capsule deep into the vagina in the morning, in the afternoon, and at night before going to bed.

If laboratory results show that you are pregnant, continue using the same dose and dosing schedule until at least the 7th week of pregnancy and no longer after the 12th week of pregnancy, as prescribed by your treating doctor.

To prevent premature birth in certain women:

Insert one capsule (200 mg) of this medicine deep into the vagina every day: in the evening before going to bed. This medicine can be given from week 20 to week 34 of pregnancy.

Have you used too much of this medicine?

If you have used more of this medicine than prescribed, contact your doctor or go to the hospital. Take the packaging of this medicine with you.

The following side effects may occur: dizziness or drowsiness.

Did you forget to use this medicine?

If you miss a dose, administer it as soon as possible. But if it is almost 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 this medicine

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

If you have any questions about 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 occur with the use of this medicine:

Frequency unknown (cannot be estimated from the available data):

itching

oily vaginal discharge

vaginal bleeding

burning sensation

Within 1-3 hours after inserting the capsule, short-term fatigue or dizziness may be experienced.

Reporting side effects

If you experience side effects, contact your treating doctor or pharmacist. This also applies to possible side effects not listed in the leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl).

By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after 'Exp.'. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not use this medicine if it looks different from what you are used to.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is progesterone. Each soft capsule contains 200 mg of progesterone.

The other substances in this medicine are sunflower oil and soy lecithin. The substances in the capsule shell are gelatin, glycerol, titanium dioxide (E171), and purified water.

What does Utrogestan 200 mg look like and how much is in a package?

Utrogestan 200 mg are oval, light yellow, soft capsules. The capsules have a white, oily content.

Each PVC/Aluminum blister pack contains 15, 21, 45, or 90 capsules. The blister packs are packaged in boxes.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer Besins Healthcare Netherlands B.V.  
Oorsprongpark 12  
3581 ET Utrecht  
Netherlands

The manufacturer of Utrogestan Vaginal:

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, plot no. 4  
50450 Muel (Zaragoza) Spain

Registered under:  
RVG 123999

This medicine is approved in the EEA member states under the following names:

Bulgaria: Utrogestan Vaginal 200 mg Capsules Denmark: Progestan

Estonia: Utrogestan 200 mg vaginaalpehmekapslid

Hungary: Utrogestan 200 mg lágy hüvelykapszula

Ireland: Utrogestan Vaginal 200mg Vaginal Capsules, soft

Iceland: Progestan 200 mg Mjúkt skeiðarhylki Italy: Utrogestan Vaginale 200 mg Capsula

molle Croatia: Utrogestan 200 mg meke kapsule za rodnicu.

Latvia: Progesterone Besins 200 mg vaginal soft capsules Lithuania: Utrogestan Besins 200 mg vaginal soft capsules  
Netherlands: Utrogestan 200 mg, soft capsules for vaginal use  
Norway: Utrogestan, 200 mg vaginal capsules, soft  
Poland: Utrogestan 200 mg, vaginal capsules, soft  
Portugal: Utrogestan Vaginal 200 mg Soft Capsule  
Slovenia: Utrogestan 200 mg soft vaginal capsules  
Slovakia: Utrogestan 200 mg soft vaginal capsules  
Spain: Utrogestan Vaginal 200 mg Soft Capsule  
Czech Republic: Progesterone Besins 200 mg soft capsules  
United Kingdom: Utrogestan Vaginal 200mg Capsules  
Sweden: Utrogestan 200 mg soft Vaginal capsule

This leaflet was last approved in March 2024.

Transtoyou