

Consumer Medicine Information

UTROGESTAN 200,

Progesterone (micronised) 200 mg, soft capsule

(For vaginal use)

What is in this leaflet

This leaflet answers some common questions about Utrogestan.

The leaflet does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Utrogestan against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Utrogestan is used for

Utrogestan is provided as a soft capsule to be inserted deep into the vagina and contains the natural female hormone, progesterone.

Utrogestan is for women who need extra progesterone while undergoing fertility treatment (e.g. ART).

Progesterone is a hormone essential for maintaining pregnancy. If you are having fertility treatment and your doctor has determined your body

does not produce enough progesterone your doctor may prescribe Utrogestan. The progesterone will help prepare your uterus (womb) to receive and maintain a fertilised egg. Once pregnancy occurs Utrogestan may be used until production of progesterone by the placenta is adequate.

Utrogestan may also be used for the prevention of preterm birth in women with singleton pregnancy who have a short cervix (midtrimester sonographic cervix ≤ 25 mm) and/or a history of spontaneous preterm birth.

There is limited evidence supporting the use of progesterone in women with twin/multiple pregnancies.

There is insufficient evidence to recommend the use of progesterone in women with preterm labour or 'other' risk factors for preterm birth.

Your doctor may have prescribed Utrogestan for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Utrogestan is available only with a doctor's prescription.

This medicine is not addictive.

Before you use Utrogestan

When you must not use it

Do not use Utrogestan if you have an allergy to:

- **any medicine containing progesterone**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include:

- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing

During fertility treatment Utrogestan should be used during the first three months of pregnancy only, unless your doctor has recommended otherwise.

For prevention of preterm birth Utrogestan may be prescribed by your Doctor during the second trimester (16-24 weeks gestation) and should be continued to the end of the 36th week of your pregnancy or until delivery.

Do not use Utrogestan if you have or have had any of the following conditions:

- if you are allergic to soya
- unusual vaginal bleeding that has not been evaluated by your doctor
- known missed abortions or ectopic pregnancy
- severe liver problems
- known or suspected cancer of the breast or genital tract

- blood clots (thrombophlebitis or thromboembolic disorder), such as inflammation of a vein, deep vein blood clotting (thrombosis) or a blood clot that travelled to the lungs (pulmonary embolism)
- bleeding on the brain
- porphyria disorder (a blood disease)

Do not use Utrogestan if you are breast-feeding.

Do not give Utrogestan to a child of any age. Utrogestan has not been evaluated in adolescents with child bearing potential.

Do not use Utrogestan after the expiry date printed on the pack.

Do not use Utrogestan if the packaging is torn, shows signs of tampering, or if the product does not look quite right.

If it has expired or if the packaging is damaged, return it to your pharmacist or doctor for disposal.

If you are not sure whether you should start using Utrogestan talk to your doctor.

Do not give this medicine to anyone else.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical

conditions, especially the following:

- epilepsy
- migraine
- high blood pressure
- asthma
- heart, liver or kidney disease
- diabetes
- history of depression.

If you have not told your doctor or pharmacist about any of the above, tell them before you use Utrogestan.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work.

Some medicines may interfere with progesterone if taken at the same time. These include:

- Carbamazepine, Phenobarbital and Phenytoin (medicines for epilepsy)
- Rifampicin
- Phenylbutazone
- Spironolactone
- Griseofulvin
- Some antibiotics including Ampicillins and Tetracyclines
- Bromocriptine
- Cyclosporin
- Ketoconazole

These medicines may be affected by Utrogestan or may affect how well they work. You may need different amounts of your medicine or you may need to use different medicines. Your doctor or pharmacist will advise you.

Utrogestan, soft capsule should not be used at the same time as other vaginal preparations.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Utrogestan.

How to use Utrogestan

How much to use

Your doctor or pharmacist will tell you how many capsules you need to use each day.

For supplementation during Assisted Reproductive Technology, the recommended dosage is 600 mg/day, in three divided doses from the day of embryo transfer until at least the 7th week of pregnancy and not later than the 12th week of pregnancy.

For the prevention of preterm birth the usual dose is 200 mg/day recommended at bedtime, during the second trimester (16-24 weeks gestation) and should be continued to the end of the 36th week of your pregnancy or until delivery.

Utrogestan is intended to be inserted into the vagina.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How long to use it

Do not stop using Utrogestan unless your doctor or pharmacist tells you to.

If you forget to use it

If it is almost time for your next dose, skip the dose you

missed and use your next dose when you are meant to, as usual.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, talk to your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Utrogestan. Do this even if there are no signs of discomfort or poisoning. Take the medicine pack with you. Symptoms of an overdose with Utrogestan include feeling dizzy or feeling tired

While you are using Utrogestan

Things you must do

Tell any other doctors or pharmacists who are treating you that you are using Utrogestan.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are using Utrogestan.

If you think you may have miscarried, you should speak to your doctor as you will need to stop using Utrogestan.

Things you must not do

Do not give Utrogestan to anyone else, even if they have the same condition as you.

Do not use Utrogestan to treat any other complaints unless your doctor has told you to.

Do not stop using Utrogestan or lower the dosage without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Utrogestan affects you.

Some people may experience drowsiness or dizziness. Make sure you know how you react to Utrogestan before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Utrogestan.

Utrogestan helps most women with low progesterone levels, but it may have unwanted side effects in a few women.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

The following is a list of possible side effects. Do not be alarmed by the list.

You may not experience any of them.

If any of the following happen, stop taking Utrogestan and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives

These are very serious side effects. If you have them, you may have had a very serious reaction to Utrogestan. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- burning,
- local itching,
- vaginal disorders

The above list includes the known side effects of the medicine. The incidence of these local side effects is extremely low.

Systemic side effects of tiredness and dizziness observed with the oral form have not been reported at the recommended dosages for vaginal use.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using Utrogestan

Storage

Keep this medicine in its original packaging until it is time to use them.

Keep this medicine in a cool dry place where the temperature stays below 30°C. DO NOT REFRIGERATE.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Utrogestan 200 soft capsule is an ovoid, slightly yellow soft capsule, containing a whitish oily suspension.

Utrogestan 200 soft capsule is supplied in blister strips packaged in an outer carton. Each carton contains 7, 14, 15, 21, 28, 30, 42, 45, 56, 84 or 90* capsules.

* Not all pack sizes may be marketed

Ingredients

Active ingredient:

- progesterone

Inactive ingredients:

- sunflower oil
- lecithin
- gelatin
- glycerol
- titanium dioxide
- purified water

Sponsor

Utrogestan is supplied in Australia by:

Besins Healthcare Australia Pty Ltd,
Level 23 Governor Macquarie Tower
1 Farrer Place, Sydney
NSW 2000

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