

Utrogestan

Progesterone 100mg, soft capsule

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Utrogestan 100mg soft capsules. It 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 taking Utrogestan 100mg soft capsules against the benefits it is expected to have for you.

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

You may need to read it again.

What Utrogestan 100mg soft capsules are used for

This medicine is provided as a soft capsule that contains the natural female hormone, progesterone, for oral use.

Utrogestan 100mg soft capsules are for women for the treatment of hormone replacement therapy (HRT) in combination with oestrogen in postmenopausal women with an intact uterus (womb)

Your doctor may have prescribed Utrogestan 100mg soft capsules for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Utrogestan 100mg soft capsules are available only with a doctor's prescription.

This medicine is not addictive.

This medicine is not a contraceptive.

Before you use Utrogestan 100mg soft capsules

When you must not take it

Do not take Utrogestan 100mg soft capsules 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

Do not take Utrogestan 100mg soft capsules if you have or have had any of the following conditions:

- unusual genital bleeding that has not been evaluated by your doctor
- 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 take oral Utrogestan if you are pregnant or intend to become pregnant.

If you get pregnant while taking oral Utrogestan, stop taking it straight away and tell your doctor.

Do not use Utrogestan 100mg soft capsules if you are breast-feeding.

Do not give Utrogestan 100mg soft capsules to a child of any age.

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

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

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

If you are not sure, talk to your doctor or pharmacist before taking Utrogestan 100mg soft capsules.

Do not give this medicine to anyone else.

Before you start to take it

Before starting or recommencing progesterone therapy, a physical examination should have been performed including special attention to the breasts, abdomen and pelvic organs.

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
- skin sensitive to light

- history of depression

If you have not told your doctor about any of the above, tell them before you use Utrogestan 100mg soft capsules.

Taking other medicines

Tell your doctor or pharmacist 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 100mg soft capsules 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Utrogestan 100mg soft capsules.

How to take Utrogestan 100mg soft capsules

How much to take

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

For women receiving hormone replacement therapy in conjunction with oestrogen with an intact uterus

(womb), the usual dose is 200 mg/day at bedtime on days 15 to 26 of your cycle. You will usually have a few days withdrawal bleeding (like a period) after this time. Alternatively 100 mg can be given at bedtime, from days 1 to 25 of each cycle, withdrawal bleeding being less with this treatment schedule.

For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used.

Whatever the indication and route of administration, the dosage should never exceed 400 mg per intake.

Utrogestan 100mg soft capsules are to be taken by mouth and swallowed whole with a glass of water.

Do not take Utrogestan 100mg soft capsules with food as this may affect the way Utrogestan works.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How long to take it

Do not stop using Utrogestan 100mg soft capsules unless your doctor or pharmacist tells you to.

If you forget to take it

If you forget to take Utrogestan 100mg soft capsules

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to, as usual.

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

Do not take 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 take your medicine, ask your pharmacist for some hints.

If you use too much (overdose):

It is important that you do not take more Utrogestan 100mg soft capsules than your doctor has prescribed. If you do take more Utrogestan 100mg soft capsules than you have been prescribed, contact your doctor for advice.

If a child accidentally swallows one or more of your Utrogestan 100mg soft capsules, immediately telephone your doctor or pharmacist or the National Poisons Centre (telephone 0800 POISON or 0800 764766) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose with Utrogestan include feeling dizzy or feeling tired.

While you are using Utrogestan 100mg soft capsules

Things you must do

Tell any other doctors or pharmacists who are treating you that you are using Utrogestan 100mg soft capsules.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are using Utrogestan 100mg soft capsules.

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even a few days after the last dosage:

- pains in your calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart or lungs
- severe headache or vomiting, dizziness, faintness or

changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye

- worsening symptoms of depression.

Things you must not do

Do not give Utrogestan 100mg soft capsules to anyone else, even if they have the same condition as you.

Do not use Utrogestan 100mg soft capsules to treat any other complaints unless your doctor has told you to.

Do not stop using Utrogestan 100mg soft capsules 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 affect you.

Some people may experience drowsiness or dizziness.

Make sure you know how you react to Utrogestan 100mg soft capsules 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.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Utrogestan 100mg soft capsules.

Utrogestan 100mg soft capsules help most women 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.

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

By oral use

- headache
- abnormal breakthrough bleeding and/or vaginal bleeding or spotting or changes in cervical secretions
- Any significant change in your menstrual cycle, including loss of menstruation
- unusual tiredness or weakness or weight gain
- acne, breast pain or tenderness,
- mild mood changes, changes in libido and insomnia

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- constipation
- breast disorders (e.g. breast pain, breast swelling and breast tenderness)
- headache, dizziness and drowsiness
- mental depression
- skin rash itchiness (pruritus)

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking Utrogestan 100mg soft capsules and tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- migraine
- loss of or change of speech, coordination or vision, pain or numbness in chest, arm or leg; unexplained shortness of breath, any symptoms of blood clots (thrombosis)
- yellowing of skin or eyes (jaundice)
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing

- Hives

These are very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare.

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.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

How to store Utrogestan 100mg soft capsules

- **Keep out of the reach and sight of children.**
- **Do not use Utrogestan 100mg soft capsules after the expiry date stated on the packaging. The expiry date refers to the last day of that month.**
- **Keep this medicine in a cool dry place where the temperature stays below 30°C. DO NOT REFRIGERATE.**
- **Store in the original blister pack and in the original outer carton.**
- **Do not store Utrogestan 100mg soft capsules, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.** Heat and dampness can destroy some medicines.
- **Keep your Utrogestan 100mg soft capsules where children cannot reach them.** A locked cupboard at least one and a half metres above the ground is a good place to store medicines.
- Medicines should not be disposed of via household waste. Ask your pharmacist how to dispose of medicines no

longer required. These measures will help to protect the environment.

Further information

What Utrogestan 100mg soft capsules contain

- The active substance is progesterone. Each capsule contains 100mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin.
- The ingredients in the capsule shell are gelatin, glycerol and titanium dioxide.

What Utrogestan 100mg soft capsules look like

- Utrogestan 100mg soft capsules, are round, soft and slightly yellow capsules.
- Capsules are supplied in cartons containing blister strips of 15 or 30 capsules.

Distributor

Utrogestan 100mg soft capsules, are distributed in New Zealand by Pharmaco (NZ) Ltd, PO Box 4079, Auckland.

This leaflet was prepared in February 2025