

Utrogestan

Progesterone capsules 100mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Utrogestan. 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 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 is used for

Utrogestan contains a hormone called progesterone and is to be used with another medicine called oestrogen. The combination of Utrogestan and oestrogen belongs to a group of medicines called hormone replacement therapy (HRT).

What Utrogestan is used for

Utrogestan is used to reduce the symptoms of the menopause (change of life).

- It is used only in women who still have a womb (uterus).

Utrogestan is not a contraceptive.

How Utrogestan works

- As you get near to the menopause, the amount of the female hormones oestrogen and progesterone in your body goes down.
- HRT, like Utrogestan, replaces these hormones and helps reduce the symptoms of the menopause.

Why Utrogestan is taken with oestrogen

- If your HRT contains only oestrogen the lining of the womb could build up. This can cause problems.
- By taking Utrogestan as well, this makes you shed the womb lining. This prevents these problems happening.
- You might get some bleeding at the end of each month, rather like a period.

Before you take Utrogestan

Medical check-ups

Before you start taking HRT, your doctor should ask about your own and your family's medical history. Your doctor may decide to examine your breasts or your tummy, and may do an internal examination. They will only do this if it is necessary for you or if you have any special concerns.

Once you have started on HRT, see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor may discuss the benefits and risks of continuing to take HRT.

Make sure that you:

- Go for regular breast screening and cervical smear tests.
- Regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

When you must not take it

Do not take Utrogestan if:

- **You are allergic (hypersensitive) to peanuts or soya. Utrogestan contains peanut oil (arachis oil).**
- You are allergic (hypersensitive) to progesterone or any of the

other ingredients of Utrogestan (listed under **How to store Utrogestan**).

- You have severe liver disease.
- You have ever had breast cancer.
- You have porphyria (an illness which makes your urine and skin an unusual colour).
- You have unexpected and unexplained bleeding from your vagina (and it is not due to your normal monthly period).
- You have ever had cancer of your sex organs (ovaries, womb, cervix, birth canal or external genitals).
- You have had blood clots, bleeding of the brain, or a stroke.

Do not take Utrogestan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Utrogestan.

A small increased risk of breast cancer may be associated with HRT use. Please refer to the CMI of the co-prescribed oestrogen for information concerning the risk.

Before you start to take it

Check with your doctor or pharmacist before taking this medicine if:

- You have high blood pressure or heart problems.
- You have kidney or liver problems.
- You have epilepsy, diabetes, migraine or asthma.
- You have ever had depression.
- Your skin is sensitive to light (photo-sensitivity).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Utrogestan.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including those from a pharmacy, supermarket or health food shop. This is because Utrogestan can affect the way some other medicines work. Also some other medicines can affect the way Utrogestan 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.
- Cyclosporin (used to suppress the immune system).
- Rifamycin medicines such as rifampicin.
- Ketoconazole (used for fungal infections).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Utrogestan.

Operations or tests

Tell your doctor if you are going to have surgery. You may need to stop taking HRT for 4 to 6 weeks before an operation to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.

Taking Utrogestan with food and drink

Do not take Utrogestan with food. See **How to take Utrogestan** for more information on when to take this medicine.

Pregnancy and breast-feeding

- Do not take Utrogestan if you are pregnant or might become pregnant.
- If you get pregnant while taking this medicine, stop taking it straight away and tell your doctor.
- Talk to your doctor before taking this medicine if you are breast-feeding.

Important information about some of the ingredients of Utrogestan

Utrogestan contains peanut oil (arachis oil) and soya lecithin.

Do not take Utrogestan if you are allergic (hypersensitive) to peanuts or soya.

How to take Utrogestan

Follow all directions given to you by your doctor or pharmacist carefully. Their directions may differ from the information contained in this leaflet. Your doctor or pharmacist will tell you how many capsules you will need to take each day. (This depends on your condition and whether or not you are taking any other medicines).

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

Taking this medicine

- Take this medicine by mouth.
- Do not take this medicine with food.
- Swallow the capsule whole with a glass of water.
- Take this medicine at bedtime.
- Take your oestrogen HRT at the same time as Utrogestan.

How much to take

- Take two capsules at bedtime on days 15 to 26 of your 28-day cycle, or alternatively, take one capsule at bedtime from day 1 to 25 of your 28-day cycle.
- You will usually have a few days withdrawal bleeding (like a period) after this time.
- Continue to take your oestrogen HRT every day.
- If you have any problems with the withdrawal bleed, your doctor may change the way that you take Utrogestan. This will help to reduce the amount of withdrawal bleeding.

If you take more Utrogestan than you should

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

If a child accidentally swallows one or more of your Utrogestan 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.

The following effects may happen: feeling dizzy, feeling tired or having a painful period.

If you forget to take Utrogestan

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

While you are using Utrogestan

Things you must do

If you become pregnant while you are taking Utrogestan tell your doctor.

If you develop unexplained or persistent pains in the head, chest, stomach or legs, you should see your doctor immediately.

Tell all doctors and pharmacists who are treating you that you are taking Utrogestan. If you are about to start taking any new medicines, tell your doctor and pharmacist that you are using Utrogestan.

If you feel that Utrogestan is not helping your condition, tell your doctor. Also, tell your doctor if, for any reason, you have not taken Utrogestan exactly as prescribed.

Things you must not do

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

Do not take Utrogestan to treat other complaints unless your doctor tells you to.

Things to be careful of

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

You may feel sleepy or dizzy while taking Utrogestan. If this happens, do not drive or use any tools or machines. Taking Utrogestan at bedtime can reduce these effects.

Possible side effects

Like all medicines, Utrogestan can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking Utrogestan and tell your doctor straight away if you notice any of the following:

- Headaches.
- Problems with your eyes.
- Yellowing of the skin or the whites of your eyes (jaundice).
- Painful swelling in your leg, sudden chest pain or difficulty breathing

See a doctor as soon as possible if you notice any of the following:

- Blood clots in the veins of your legs or pelvis.
- Changes in your breast such as dimpling of the skin, changes in the nipples, any lumps

Other side effects include:

- Feeling tired or dizzy.
- Difficulty sleeping.
- High temperature.
- Depression.
- Feeling sick or having an upset or bloated stomach.
- Changes to your menstrual flow or bleeding at times other than the withdrawal bleed. If this happens, your doctor may change the way you take your medicine.
- Pre-menstrual symptoms such as irritability, backache or lower stomach pain.
- Changes to your breasts. They may become tender.
- Changes in secretions from your genitals.
- Changes in your libido (interest in sex).
- Changes to your weight or swollen ankles.
- Loss of hair or an increase in hair growth.

- Rash (which may be itchy) or other changes in your skin such as acne.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

How to store Utrogestan

- Keep out of the reach and sight of children.
- Do not use Utrogestan after the expiry date stated on the packaging. The expiry date refers to the last day of that month.
- Store in the original blister pack and in the original outer carton.
- **Do not store Utrogestan, 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 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 Capsules contain

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

What Utrogestan 100mg Capsules look like

- Utrogestan 100mg Capsules are soft and white.
- They are supplied in cartons containing blister strips of 30 capsules.

Distributor

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

This leaflet was prepared in May 2011.