

PACKAGE LEAFLET: INFORMATION FOR THE USER

Utrogestan® 100 mg Capsules

progesterone

Read all of this leaflet carefully before you start taking 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 is and what it is used for
2. What you need to know before you take Utrogestan
3. How to take Utrogestan
4. Possible side effects
5. How to store Utrogestan
6. Contents of the pack and other information

1. What Utrogestan is and what it is used for

The name of your medicine is Utrogestan 100 mg Capsules (called Utrogestan in this leaflet). Utrogestan contains a female hormone called progesterone and is to be used with another medicine called estrogen. The combination of Utrogestan and estrogen belongs to a group of medicines called hormone replacement therapy (HRT).

What Utrogestan is used for

Utrogestan in combination with an estrogen 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 estrogen and progesterone in your body goes down.
- HRT replaces these hormones and helps reduce the symptoms of the menopause.

Why Utrogestan is taken with estrogen

- If your HRT contains only estrogen 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.

2. What you need to know before you take Utrogestan

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts, and/or an internal examination, if necessary.

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

Go for regular breast screening, as recommended by your doctor.

Do not take Utrogestan if any of the following applies to you. If you are not sure about any of the points below, talk to your doctor or pharmacist before taking Utrogestan.

Do not take Utrogestan:

- If you are **allergic** (hypersensitive) to progesterone or any of the other ingredients of this medicine (listed in Section 6).
- If you have ever had **breast cancer**, or if you are suspected of having it;
- If you have **cancer which is sensitive to estrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it;
- If you have any **unexplained vaginal bleeding**;
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism);
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency);
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke** or **angina**;
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal;
- If you have a rare blood problem called **“porphyria”** which is passed down in families (inherited);
- If you have bleeding on the brain (**cerebral haemorrhage**);
- If you are **breast-feeding** (see ‘Pregnancy and Breast-feeding’);
- If you are allergic (hypersensitive) to soya.

If any of the above conditions appear for the first time while taking Utrogestan, stop taking it at once and consult your doctor immediately.

Warnings and precautions

Talk to your doctor or pharmacist before taking Utrogestan.

When to take special care with HRT

Tell your doctor if you have or ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with HRT. If so, you should see your doctor for more often check-ups:

- Abnormal tumours/growths (fibroids inside your womb);
- Growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia);
- Increased risk of developing blood clots (see “Blood clots in a vein (thrombosis)”);
- Increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer);
- High blood pressure;
- Liver problems such as benign liver tumour;
- Diabetes;
- Gallstones;

- Migraine or severe headaches;
- A disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE);
- Epilepsy;
- Asthma;
- A disease affecting the eardrum and hearing (otosclerosis);
- You have ever had depression;
- Your skin is sensitive to light (photo-sensitivity).

Stop taking Utrogestan and see a doctor immediately

If you notice any of the following when taking HRT:

- Any of the conditions mentioned in the ‘DO NOT take Utrogestan’ section;
- Yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease;
- A large rise in your blood pressure (symptoms may be headache, tiredness, dizziness);
- Migraine-like headaches which happen for the first time;
- Sudden or gradual, partial or complete loss of vision;
- Forward displacement of the eye (proptosis) or double vision (diplopia);
- Swelling of the optic nerve (papilloedema);
- Eye diseases (retinal vascular lesions);
- If you become pregnant;
- If you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs;
 - sudden chest pain;
 - difficulty in breathing;

For more information, see ‘Blood clots in a vein (thrombosis)’

Note: Utrogestan is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking estrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer). The progestogen in Utrogestan protects you from this extra risk.

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking Utrogestan. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- carries on for more than the first 6 months;
- starts after you have been taking Utrogestan more than 6 months;
- carries on after you have stopped taking Utrogestan;

See your doctor as soon as possible

Breast cancer

Evidence suggests that taking combined estrogen-progestogen and possibly also estrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

Compare

Women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking estrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 4 to 6 cases).

Regularly check your breasts. See your doctor if you notice any changes, such as:

- Dimpling of the skin.
- Changes in the nipple.
- Any lumps you can see or feel.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

Ovarian cancer is rare – much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3-times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- You are unable to walk for a long time because of major surgery, injury or illness (see also section 3, ‘If you need to have surgery’);
- You are seriously overweight (BMI > 30 kg/m²);
- You have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots;
- If any of your close relatives has ever had a blood clot in the leg, lung or another organ;
- You have systemic lupus erythematosus (SLE);
- You have cancer.

For signs of a blood clot, see “Stop taking Utrogestan and see a doctor immediately”.

Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein. For women in their 50s who have been taking estrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

Heart disease (heart attack)

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke

The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions

HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Children

Utrogestan is not for use in children.

Other medicines and Utrogestan

Utrogestan can affect the way some other medicines work. Also some medicines may interfere with the effect of

Utrogestan. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine);
- Medicines for **tuberculosis** (such as rifampicin, rifabutin);
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir);
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*);
- Bromocriptine used for problems with the pituitary gland or Parkinson's Disease;
- Ciclosporin (used to suppress the immune system);
- Ketoconazole, griseofulvin, terbinafine (used for fungal infections);
- Water tablets (spironolactone);
- Antibiotics (ampicillins, tetracyclines);
- Antisteroids (medroxyprogesterone acetate, megestrol)
- Medicines to prevent blood clots (such as coumarins, phenindione)
- Diabetic medicines
- Emergency contraceptives (ulipristal acetate)
- Diazepam
- Tizanidine (used in multiple sclerosis)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking HRT, because HRT can affect the results of some tests.

Utrogestan with food and drink

Do not take Utrogestan with food. See Section 3 '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.
- Utrogestan is for use in postmenopausal women only. If you become pregnant, stop taking Utrogestan and contact your doctor.
- Talk to your doctor before taking this medicine if you are breast-feeding.

Driving and using machines

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.

Utrogestan contains soybean lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Utrogestan

Always take this medicine exactly as your doctor has told you. Always read the label. Check with your doctor or pharmacist if you are not sure.

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

The recommended dose is 200 mg daily at bedtime, for twelve days in the last half of each therapeutic cycle (beginning on Day 15 of the cycle and ending on Day 26).

Alternatively, 100 mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle.

Taking this medicine

- Take this medicine by mouth.
- Swallow the capsule whole with a glass of water.
- Take this medicine at bedtime.
- Do not take this medicine with food.
- Take your estrogen 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.
- You will usually have a few days withdrawal bleeding (like a period) after this time.
- Continue to take your estrogen 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 need to have surgery

If you are going to have surgery, tell the surgeon that you are taking HRT. You may need to stop taking HRT about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clot in a vein). Ask your doctor when you can start taking HRT again.

If you take more Utrogestan than you should

If you take more Utrogestan than you should, talk to your doctor or go to a hospital. Take the medicine pack with you. The following effects may happen: feeling drowsy, dizzy, sleepy or tired.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- Breast cancer;
 - Abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer);
 - Ovarian cancer;
 - Blood clots in the veins of the legs or lungs (venous thromboembolism);
 - Heart disease;
 - Stroke;
 - Probable memory loss if HRT is started over the age of 65;
- For more information about these side effects, see Section 2.

The following side effects have been reported since Utrogestan came on the market and may happen with

Utrogestan taken orally:

Frequency not known (frequency cannot be estimated from the available data):

- Stomach pain
- Nausea (sickness in the stomach)
- Tiredness
- Headache
- Drowsiness
- Dizziness
- Vaginal bleeding
- Intense itching (pruritus)

During clinical trials, the following side effects have also been observed:

Frequency not known (frequency cannot be estimated from the available data):

- Bloating of the stomach
- Depression
- Breast tenderness
- Hot flashes
- Vaginal discharge
- Joint pain
- Urinary problems

The following side effects have been reported with other HRTs:

- Gall bladder disease
- Various skin disorders
 - Discolouration of the skin especially of the face or neck known as "pregnancy patches" (chloasma)
 - Painful reddish skin nodules (erythema nodosum)
 - Rash with target-shaped reddening or sores (erythema multiforme)
- Breast pain (mastodynia)
- Fluid retention (oedema)
- Weight changes
- Increase or decrease in sexual desire
- Depression
- Rashes
- Urticaria (itchy, lumpy rash)
- Patchy brown or dark brown skin discolouration (Melasma)
- Fever
- Insomnia (inability to obtain an adequate amount or quality of sleep)
- Alopecia (hair loss)
- Irregular menstruation
- Lack of menstrual periods

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Utrogestan

- Keep this medicine 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.
- Do not store above 25°C.
- Store in the original blister pack and in the original outer carton in order to protect from light.
- 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 protect the environment.

6. Content of the pack and other information

What Utrogestan 100 mg Capsules contain

- The active substance is progesterone. Each capsule contains 100 mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin. The other ingredients in the capsule shell are gelatin, glycerol and titanium dioxide (E171).

What Utrogestan 100 mg Capsules look like and contents of the pack

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

Parallel Product Authorisation holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

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