

PATIENT INFORMATION LEAFLET
UTROGESTAN 200mg 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. Content of the pack and other information

1. What Utrogestan is and what it is used for

The name of your medicine is Utrogestan 200mg Capsules (called Utrogestan in this leaflet). 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.

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, your tummy and/or an internal examination, if necessary.

Once you have started on HRT, 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 have ever had **breast cancer**, or if you are suspected of having it;
- If you have **cancer which is sensitive to oestrogens**, 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 **cerebral haemorrhage**;
- You are allergic (hypersensitive) to progesterone or any of the other ingredients of this medicine (listed in Section 6).
- 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

When to take special care with HRT

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

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:

- 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 a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer);
- Gallstones;
- Severe headaches;
- A disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE);
- A disease affecting the eardrum and hearing (otosclerosis);
- A very high level of fat in your blood (triglycerides);
- Fluid retention due to cardiac or kidney problems.

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;
- Proptosis (forward displacement of the eye) or diplopia (double vision);
- Papilloedema (swelling of the optic nerve);
- Retinal vascular lesions (eye diseases);
- 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

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 oestrogen-progestogen and possibly also oestrogen-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 oestrogen-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. A slightly increased risk of ovarian cancer has been reported in women taking HRT for at least 5 to 10 years.

Women aged 50 to 69 who are not taking HRT, on average about 2 women in 1000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be between 2 and 3 cases per 1000 users (i.e. up to 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 oestrogen-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 oestrogen-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 other medicines may interfere with the effect of Utrogestan or HRT. This applies to the following medicines:

- Medicines for epilepsy (such as phenobarbital, phenytoin and carbamazepin);
 - 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.
 - Cyclosporin (used to suppress the immune system).
 - Ketoconazole (used for fungal infections).
- Please tell your doctor or pharmacist if you are taking or have recently taken 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 soya lecithin

Utrogestan contains soya lecithin. Do not take Utrogestan if you are allergic (hypersensitive) to soya.

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).

Taking this medicine

- Take this medicine by mouth.
- 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 one capsule 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 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 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 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.

If you stop taking Utrogestan

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 side effects may happen with this medicine. 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 may happen with Utrogestan taken orally:

Common side effects (more than 1 patient of 100 and less than 1 of 10)

- Altered periods;
- Amenorrhoea;
- Intercurrent bleeding;
- Headaches.

Uncommon side effects (more than 1 patient of 1 000 and less than 1 of 100)

- Mastodynia;
- Drowsiness;
- Dizziness;
- Vomiting;
- Diarrhoea;
- Constipation;
- Cholestatic jaundice (yellowing of the skin and eyes);
- Pruritus (intense itching);
- Acne.

Rare (more than 1 patient of 10 000 and less than 1 of 1 000)

- Nausea (sickness in the stomach).

Very rare (less than 1 patient of 10 000)

- Depression;
- Urticaria (itchy eruption of the skin);
- Chloasma (patchy brown or dark brown skin discoloration).

The following side effects have been reported with other HRTs:

Rashes (group of spots or red, inflamed skin), weight changes, change in libido (increase or decrease in sexual desire), pyrexia (fever), insomnia (inability to obtain an adequate amount or quality of sleep), alopecia (hair loss), hirsutism (excessive growth of facial or body hair), gall bladder disease, various skin disorders as erythema nodosum (painful reddish skin nodules), erythema multiform (rash with target-shaped reddening or sores).

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 the website www.mhra.gov.uk/yellowcard. 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 stated on the packaging after 'Exp'. 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 throw away any medicines via wastewater. 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 200mg Capsules contain

- The active substance is progesterone. Each capsule contains 200mg progesterone.
- The other ingredients are sunflower oil and soybean lecithin. The other ingredients in the capsule shell are gelatin, glycerol and titanium dioxide.

What Utrogestan 200mg Capsules look like

- Utrogestan 200mg Capsules are soft and white.
- They are supplied in cartons containing blister strips of 15 capsules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Utrogestan 200mg Capsules is held by Besins Healthcare - Avenue Louise, 287-1050 Brussels - Belgium

Utrogestan 200mg Capsules are manufactured by Besins Manufacturing Belgium, Groot Bijgaardenstraat 128,1620 Drogenbos, Belgium Cyndea Pharma, S.L. Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110 (Soria), Spain.

Distributed in the UK by

Besins Healthcare (UK) Ltd,
1st Floor, 28 Poland Street,
London - W1F 8QN,
United Kingdom
Tel. +44(0)203862 0920
Licence number PL 28397/0004

This leaflet was last revised in Aug 2016.

For information in large print, tape, CD or Braille, telephone +44(0)203862 0920.