

PATIENT INFORMATION LEAFLET
UTROGESTAN 100mg CAPSULES
Progesterone

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What Utrogestan is and what it is used for
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3. Safety of HRT
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1. What Utrogestan is and what it is used for

The name of your medicine is Utrogestan 100mg 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. Before you take Utrogestan

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 in Section 7).
- 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.

Take special care with Utrogestan

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.

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.

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 herbal medicines. 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 Section 4 '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.

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.

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.

3. Safety of HRT

As well as benefits, HRT has some risks which you need to consider when you're deciding whether to take it, or whether to carry on taking it.

Risk of developing cancer

Breast cancer

Women who have breast cancer, or have had breast cancer in the past, should not take HRT.

Taking HRT for 5 years or more slightly increases the risk of breast cancer. The risk is also slightly increased if you have a later menopause. The risk for a post-menopausal woman taking HRT for 5 years is about the same as for a woman of the same age who is still having periods over that time and not taking HRT. The risk for a woman who is taking oestrogen plus progesterone HRT is higher than for oestrogen-only HRT. However, oestrogen plus progesterone HRT is beneficial for the lining of the womb.

For all kinds of HRT, the extra risk of breast cancer goes up the longer you take it. However, it returns to normal about 5 years after stopping HRT.

Your risk of breast cancer is also higher if:

- You have a close relative (mother, sister or grandmother) who has had breast cancer.
- You are seriously overweight.

How likely is breast cancer?

Looking at women aged 50, on average, by the time they reach 70:

- Women **not taking HRT: 45 in 1000** would be expected to get breast cancer.
- Women **taking HRT for 5 years: 47 in 1000** would be expected to get breast cancer. This means an extra 2 cases.
- Women **taking HRT for 10 years: 51 in 1000** would be expected to get breast cancer. This means an extra 6 cases.
- Women **taking HRT for 15 years: 57 in 1000** would be expected to get breast cancer. This means an extra 12 cases.

If you notice any **changes in your breast**, such as:

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

Make an appointment to see your doctor as soon as possible.

Heart or circulation

Blood clots

HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis or DVT), especially during the first year of taking it.

These blood clots are not always serious, but if one travels to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called pulmonary embolism, or PE.

DVT and PE are examples of a condition called venous thromboembolism, or VTE.

You are more likely to get a blood clot if:

- You are seriously overweight.
- You have had a blood clot before.
- Any of your close family have had blood clots.
- You have any blood clotting problems that need treatment with a medicine such as warfarin.
- You are off your feet for a long time because of major surgery, injury or illness.

If any of these apply to you, talk to your doctor to see if you should take HRT.

How likely is a blood clot?

Looking at women in their 50s, on average, over 5 years:

- Women **not taking HRT: 3 in 1000** would be expected to get a blood clot.
- Women **taking HRT: 7 in 1000** would be expected to get a blood clot.

Looking at women in their 60s, on average, over 5 years:

- Women **not taking HRT: 8 in 1000** would be expected to get a blood clot.
- Women **taking HRT: 17 in 1000** would be expected to get a blood clot.

If you get painful swelling in your leg, sudden chest pain or difficulty breathing **see a doctor as soon as possible**. Do not use any more HRT until a doctor says you can. These may be signs of a blood clot.

4. How to take Utrogestan

Always take Utrogestan exactly as your doctor has told you. Always read the label. You should check with your doctor or pharmacist if you are not sure.

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 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.

5. 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).

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

- Blood clots in the veins of your legs or pelvis (see Section 3 'Safety of HRT' above).
- You have any of the problems listed in Section 3 'Safety of HRT' above.

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.

6. 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.
- Medicines should not be disposed of via household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. 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 other 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.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Utrogestan 100mg Capsules is held by Laboratoires Besins International, 3, rue du Bourg l'Abbé, 75003 PARIS, France.

Utrogestan 100mg Capsules are manufactured by Laboratoires Besins International, 13, rue Périer 92120, Montrouge, France and Besins Manufacturing Belgium, Groot Bijgaardenstraat 128, 1620 Drogenbos, Belgium.

Utrogestan 100mg Capsules are distributed in the UK by Ferring Pharmaceuticals Ltd., The Courtyard, Waterside Drive, Langley, Berkshire SL3 6EZ.

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