

Package leaflet: Information for the user

Progesterone 200 mg Capsules, soft

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 Progesterone is and what it is used for
2. What you need to know before you take Progesterone
3. How to take Progesterone
4. Possible side effects
5. How to store Progesterone
6. Contents of the pack and other information

1. What Progesterone is and what it is used for

The name of your medicine is Progesterone 200 mg Capsules, soft (called Progesterone throughout this leaflet). These capsules contain a female hormone called progesterone and is to be used with another medicine called estrogen. The combination of progesterone and estrogen belongs to a group of medicines called **hormone replacement therapy (HRT)**.

What Progesterone is used for

Progesterone 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). Progesterone is not a contraceptive.

How Progesterone 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 Progesterone is taken with estrogen

- If your HRT contains only estrogen the lining of the womb could build up. This can cause problems.
- By taking progesterone 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 Progesterone

Do not take Progesterone

- if you are allergic 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 (chest pain)
- 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 Progesterone, stop taking it at once and consult your doctor immediately.

Warnings and precautions

Talk to your doctor or pharmacist before taking Progesterone.

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.

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

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking progesterone. 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 progesterone more than 6 months
- carries on after you have stopped taking progesterone.

Stop taking Progesterone 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 Progesterone' 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)'.

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.

For signs of a blood clot, see "Stop taking Progesterone and see a doctor immediately".

Note:

Progesterone 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. Talk 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). Progesterone protects you from this extra risk.

Stroke

You will have a bleed once a month (so-called withdrawal bleed) while taking progesterone. 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 progesterone more than 6 months
- carries on after you have stopped taking progesterone.

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 they travel 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 ($BM > 30 \text{ kg/m}^2$)
- 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 have 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 Progesterone and see a doctor immediately".

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.

For signs of a blood clot, see "Stop taking Progesterone and see a doctor immediately".

Note:

Progesterone 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. Talk to your doctor for advice.

Other conditions

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).

Other medicines and progesterone

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.

Progesterone can affect the way some other medicines work. Also some medicines may interfere with the effect of progesterone. 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 nevirapine)
- Herbal medicines containing St John's wort (*Hypericum perforatum*)
- Hormone used for problems with the pituitary gland and Parkinson's Disease
- Ciclosporin (used to suppress the immune system)
- Ketoconazole, griseofulvin, tribrinafine (used for fungal infections)
- Anteratables (spermicides)
- Antibiotics (amoxicillin, tetracyclines)
- Antiseptics (mercuric chloride)
- Medicines to prevent blood clots (such as coumarins, heparin)

- Diabetic medicines
- Emergency contraceptives (ulipristal acetate)
- Diazepam
- Tizanidine (used in multiple sclerosis).

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.

Progesterone with food and drink

Do not take Progesterone with food. See section 3 'How to take Progesterone' for more information on when to take this medicine.

Pregnancy and breast-feeding

- Do not take progesterone if you are pregnant or might become pregnant.
- Progesterone is for use in postmenopausal women only.
- If you become pregnant, stop taking progesterone 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 progesterone. If this happens, do not drive or use any tools or machines. Taking progesterone at bedtime can reduce these effects.

Progesterone contains soyabean lecithin

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

3. How to take Progesterone

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 a time 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, a 100 mg capsule 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 progesterone.

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 estrogen HRT every day.

If you have any problems with the withdrawal bleed, your doctor may change the way that you take progesterone. 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 Progesterone than you should

If you take more Progesterone 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 Progesterone

- 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 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 have been reported since progesterone came on the market and may happen when this medicine is taken orally:

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

- stomach pain
- nausea (sickness in the stomach)
- tiredness
- headache
- drowsiness (sleepiness)
- dizziness
- vaginal bleeding
- intense itching (pruritus).

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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Progesterone

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 blister pack and the carton. The expiry date refers to the last day of that month.

Store below 25°C.

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. Contents of the pack and other information

What Progesterone contains

- The active substance is progesterone. Each capsule contains 200 mg micronised progesterone.

What Progesterone looks like and contents of the pack

Progesterone 200 mg capsules, soft, are off white opaque, oval shaped soft gelatin capsules, containing an off white to white coloured suspension, length 15.5 mm and width 9.5 mm.

Each pack contains blister strips of 30 or 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited,
12 New Fetter Lane,
London,
EC4A 1JP,
United Kingdom

Manufacturer

Zentiva Pharma UK Limited,
First Floor, Andrews House,
College Road, Guildford,
GU1 4QB, United Kingdom

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