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 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 Progesterone.

Do not take Progesterone
- if you are **allergic** (hypersensitive) to progesterone, soya, peanut 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 excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- 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 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, 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.

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)
- A very high level of fat in your blood (triglycerides)
- Fluid retention due to cardiac or kidney problems
- Hereditary and acquired angioedema
- You have ever had depression
- Your skin is sensitive to light (photo-sensitivity).

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)'.

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. 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). Progesterone protects you from this extra risk.

Unexpected bleeding
You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of taking this medicine. However, if the irregular bleeding;
- 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.

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/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 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 Progesterone 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
Progesterone is not for use in pre-pubescent children.

Other medicines and progesterone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- blood thinners such as coumarins or phenindione
- ciclosporin or tacrolimus (used to reduce the immune response)
- tizanidine (muscle relaxant)
- bromocriptine, which is used in the treatment of pituitary gland-related problems or Parkinson's disease
- selegiline (for treating Parkinson's disease)
- diazepam, chlordiazepoxide, alprazolam, oxazepam or lorazepam (for treating anxiety or insomnia)
- tuberculosis medicines (such as rifampicin and rifabutin)
- antibiotics (for example ampicillin, amoxicillin and tetracyclines), which are used to treat certain infections
- phenytoin, phenobarbital, carbamazepine, eslicarbazepine, oxcarbazepine, primidone/rufinamide, perampanel or topiramate (used for treating epilepsy)
- herbal medicine products containing St John's Wort
- darunavir, nelfinavir, fosamprenavir or lopinavir (used to treat viral infections)
- bosentan (used to treat lung problems)
- fluconazole, itraconazole, voriconazole, ketoconazole (for the treatment of fungal infections)
- atorvastatin or rosuvastatin (used to control cholesterol)
- aprepitant (used to prevent nausea and vomiting).

Tell your doctor or pharmacist:
- if you have recently been given an anaesthetic, such as bupivacaine or
- if you have recently been tested for liver or hormone problems.

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

Progesterone 200 mg Capsules contain highly refined oil, which very rarely causes a reaction in adults allergic to refined oils.

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 dizzy, feeling tired or having a painful period.

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 stop taking Progesterone
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 this medicine:

Common side effects (may affect up to 1 in 10 people)
- Weight changes
- Insomnia (difficulty falling and staying asleep, poor quality of sleep),
- Feeling tired or dizzy (see also section 'Driving and using machines').
- Headaches,
- Abdominal swelling or pain,
- Feeling sick (nausea),
- Itching,
- Irregular or intermenstrual bleeding,
- Vaginal bleeding,
- Breast pain or tenderness,
- Missing or absent periods,
- Tiredness,
- Feeling generally unwell.

Uncommon side effects (may affect up to 1 in 100 people)
- Problems due to the formation of blood clots in the blood vessels (thromboembolic disorders),
- Fluid retention,
- Feeling agitated or anxious,
- Lack of interest or energy,
- Depression,
- Disorientation,
- Mood swings,
- Nervousness,
- Memory loss,
- Migraine,
- Sensations like numbness, tingling, pins and needles,
- Speech disorder,
- Fainting,
- Changes in your vision,
- Ringing or buzzing in the ears,
- A spinning sensation,
- Palpitations or rapid heartbeat,
- Hot flush,
- Low blood pressure,
- Difficulty breathing,
- Being sick (vomiting),
- Diarrhoea,
- Constipation,
- Non-severe and reversible liver disorders,
- Yellowing of the skin or the whites of your eyes (jaundice),
- Acne,
- Hair loss,
- Reddening of the skin,
- Excessive sweating,
- Itchy skin or rash,
- Joint, back or muscle pain,
- Muscle spasms,
- Abnormal menstrual cycle,
- Breast discomfort,
- Irregular thickening of the uterine lining (endometrial hyperplasia),
- Vaginal discharge,
- A burning pain or discomfort in the vulva,
- Breast tenderness,
- Excessive hair (where there is usually very little or no hair),
- Weakness,
- Chest discomfort or pain,
- Swelling.

Rare side effects (may affect up to 1 in 1,000 people)
- Change in glucose tolerance,
- Change in libido,
- Eye irritation,
- Loss of appetite,
- Painful urination.

Very rare side effects (may affect up to 1 in 10,000 people)
- Tan or dark skin discoloration (so-called mask of pregnancy),
- Allergic reactions.

Not known (frequency cannot be estimated from the available data):
- Infection of the parts of the body that collect and pass out urine (urinary tract infection),
- An inflammation of the vagina that can result in discharge, itching and pain (vaginitis),
- Taste disturbance,
- Period pains,
- Unexpected vaginal bleeding, spotting or blood streaked discharge,
- Fever.

The following side effects have been reported with other HRTs:
- gall bladder disease
- various skin disorders
  - discoloration 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 discoloration (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 the 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 stated on the packaging after 'Exp'. 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.
- The other ingredients are sunflower oil (refined), soyabean lecithin, gelatin, glycerol, titanium dioxide and purified water.

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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