

Package leaflet: Information for the user

Prometrium 400mg soft vaginal capsules

progesterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Use this medicine exactly as described in this package leaflet or as your doctor, pharmacist or nurse have instructed.

- Keep this leaflet. You may need to read it again.
- If you have questions, consult your doctor, pharmacist or nurse.
- 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 notice any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Prometrium is and what it is used for

The name of your medicine is Prometrium 400mg soft vaginal capsules (called Prometrium in this package leaflet). Prometrium contains a hormone called progesterone.

What Prometrium is used for

Prometrium can be used to help pregnancy.

To help pregnancy

Prometrium can be used to help women reduce the risk of miscarriage in women with bleeding in the current pregnancy and a history of recurrent miscarriages.

2. What you need to know before you use Prometrium

Do not use Prometrium

- if you are allergic (hypersensitive) to soya or peanuts
- if you are allergic to progesterone or any of the other ingredients of this medicine (listed in section 6)
- if you have liver problems
- if you have yellowing of the skin or eyes (jaundice)
- if you have undiagnosed vaginal bleeding

- if you have breast cancer or cancer of the genitals
- if you have or have had blood clots in a vein (thrombosis), which can sometimes be painful (thrombophlebitis), for example in the leg (deep vein thrombosis) or the lungs (pulmonary embolism)
- if you have had a cerebral haemorrhage or stroke
- if you have a rare blood disease called porphyria, which is passed down in families (inherited).

Warnings and precautions

Prometrium should only be used during the first 3 months of pregnancy. Talk to your doctor or pharmacist or nurse or mid-wife before using Prometrium.

Prometrium is not a contraceptive.

If you believe that you have had a miscarriage, you must speak with your doctor, because you must stop using Prometrium .

You must contact your doctor if you:

- experience any vaginal bleeding
- feel unwell within a few days of taking the medicine.

Children and adolescents

Prometrium is not for use in children.

Other medicines and Prometrium

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. This is because Prometrium can affect the way some other medicines work. Also some other medicines can affect the way Prometrium works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- ciclosporin (used to reduce the immune response).
- bromocriptine, which is used in the treatment of pituitary gland-related problems or Parkinson's disease.
- Rifamycin medicines such as rifampicin (used to treat infections).
- Ketoconazole (used for fungal infections).

If you have recently been tested for liver or hormone problems.

Prometrium with food and drink

Prometrium should be inserted into the vagina. Food and drinks do not affect the treatment.

Pregnancy and breast-feeding

Do not use Prometrium if you are breast-feeding.

Driving and using machines

If this medicine makes you feel drowsy then do not drive or use machinery.

Prometrium contains soybean lecithin

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

3. How to use Prometrium

Always use this medicine exactly as instructed by your doctor. If you have adverse reactions, check with your doctor, pharmacist or nurse or mid-wife.

For treatment to reduce the risk of miscarriage in women with bleeding in the current pregnancy Prometrium should be initiated at the first sign of vaginal bleeding during the first trimester and should continue at least until the 16th week of pregnancy.

Using this medicine to reduce the risk of threatened or recurrent miscarriage

- Insert this medicine deep into the vagina.
- Do not swallow.

How much Prometrium to use

- Take one Prometrium capsule twice daily, one in the morning and one at bedtime, or as instructed by your doctor.
- Continue with the same dose regimen until your doctor tells you to stop.

If you use more Prometrium than you should

If you have used too much Prometrium, you should talk to your doctor or go to a hospital. Take the medicine pack with you.

The following effects may happen: feeling dizzy or feeling tired.

If you forget to use Prometrium

- If you forget to insert a dose, insert it as soon as you remember. However, if it is nearly time for your next dose, you can skip the missed dose.
- Do not take a double dose to compensate for a forgotten dose.

If you stop using Prometrium

Talk to your doctor, pharmacist or nurse or mid-wife before stopping this medicine.

If you have questions regarding the use of this medicine, talk to your doctor or pharmacist or nurse or mid-wife.

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:

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

- Itching or burning sensation
- Oily discharge from the vagina.

You may experience short-term tiredness or dizziness within 1 – 3 hours of using the medicine.

If you notice side effects other than those mentioned above, tell your doctor or pharmacist, nurse or mid-wife.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse or mid-wife. This includes any possible side effects not listed in this leaflet. You can also report side effects via the website 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 Prometrium

- Keep this medicine out of the sight and reach of children.
- Do not use this product after the expiry date which is stated in the carton after EXP. The expiry date refers to the last day of that month.
- Store in the original packaging (the bottle)
- 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 to protect the environment.
- Do not use this medicine if you notice any changes in the appearance of the capsules

6. Contents of the pack and other information

What Prometrium contains

- Active substance is progesterone. One capsule contains 400mg of progesterone.
- The other ingredients in the capsule are sunflower oil, soyabean lecithin, gelatine, glycerol (E422), titanium dioxide (E171) and purified water.

What Prometrium looks like and package sizes

The capsules are yellowish, soft gelatin capsules, that contain a whitish oily suspension. The dimensions of the 400mg capsule are approximately 2.5 cm x 0.9 cm.

Pack size: 15 capsules per bottle (HDPE). The bottle is supplied in a cardboard carton.

Marketing Authorisation Holder

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Manufacturer

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