

Package leaflet: Information for the user

Progesterone 200mg Pessaries

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. **What Progesterone pessaries are and what they are used for**

Progesterone is a natural, female sex hormone, produced in the body. Progesterone works by adjusting the hormonal balance within the body for the treatment of:

- pre-menstrual syndrome which often affects women during the 7 to 10 days before their monthly period. The symptoms of pre-menstrual syndrome include feelings of tension, irritability, depression, headache, breast tenderness, weight gain and bloatedness
- post-natal depression which some women get after their baby has been born.

2. **What you need to know before you use Progesterone pessaries**

Do not use Progesterone pessaries if you:

- are **allergic** to progesterone or any of the other ingredients of this medicine (listed in section 6),
- have unusual vaginal **bleeding** that has not been evaluated by the doctor,
- have known or suspected **tumour** that is hormone sensitive,
- have **porphyria** disorders (a group of inherited or acquired disorders of certain enzymes),
- have or have had blood **clots** in the legs, lungs, eyes or elsewhere in the body,
- currently have or have had severe **liver problems**.
- have a **miscarriage** and your physician suspects some tissue is still in the uterus or pregnancy outside of the womb.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Progesterone pessaries.

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even few days after the last dosage:

- pains in the calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart, or lungs
- severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg indicating possible clots in the brain or eye
- worsening of depression

Check with your doctor or pharmacist before using Progesterone pessaries if you have or ever have had:

- liver problems such as jaundice (yellowing of the skin and whites of the eyes)
- epilepsy
- migraine
- asthma
- cardiac or renal dysfunction
- diabetes

Children

There is no relevant use of Progesterone pessaries in children.

Other medicines and Progesterone pessaries

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important in case you are taking carbamazepine (e.g. to prevent fits, treat certain type of pain or mood disorders), rifampicin (to treat infections) or phenytoin (e.g. to prevent fits or treat certain type of pain) as they may decrease the effectiveness of progesterone.

Using other vaginal products at the same time as Progesterone pessaries is used vaginally is not recommended as it is not known if it affects the treatment.

Pregnancy and breast-feeding

The risks of congenital (conditions present at birth) anomalies, including genital abnormalities in male or female infants, from exposure to exogenous progesterone during pregnancy have not been fully established.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

This medicine should not be used during breast feeding.

3. How to use Progesterone pessaries

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 200 mg once a day or 400 mg twice a day by vaginal or rectal insertion.

The pessary may be inserted into either the vagina or rectum (back passage) depending upon the following certain other conditions.

You should insert Progesterone pessaries into the:

- **vagina** if you have:
 - colitis (inflammation of the colon causing frequent attacks of diarrhoea with mucous or blood)
 - problems controlling your bowel movements (faecal incontinence).
- **rectum** (back passage) if you have:
 - a vaginal infection (discharge from your vagina)
 - or often have cystitis (a burning pain on passing water)
 - recently given birth
 - to use a barrier method of birth control such as a diaphragm, cap or condom. Such devices may not work properly in the presence of the vegetable fat from the pessary.

For premenstrual tension start using Progesterone pessaries on day 12 or 14 of your menstrual cycle. This can be planned and marked onto your calendar, day 1 is the first day of your monthly period, counting forward to day 12 or 14 as advised by your doctor.

Do not swallow Progesterone pessaries.

How to insert Progesterone pessaries

Always wash your hands before and after inserting the pessary.

To insert into the:

- **Vagina** - place the pessary between the lips of the vagina and push the pessary upwards and backwards. You may find it easier to do this if you are lying down or squatting.
- **Rectum (back passage)** - gently push the pessary into the rectum for about one inch. Your muscles will hold the pessary in place when it is in far enough. Squeeze your buttocks together for a few seconds.

If you use more Progesterone pessaries than you should

If you (or someone else) has accidentally swallowed any of the pessaries or you use too many, contact your nearest hospital casualty department or your doctor immediately for advice.

If you forget to use Progesterone pessaries

If you forget to insert a pessary, do so as soon as you remember, unless it is nearly time for the next dose. Never use two doses together. Remember to use the remaining doses at the correct time.

If you stop using Cyclogest

Please consult your doctor or pharmacist for advice if you intend to stop or have stopped using Cyclogest. Abrupt discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensibility to seizures.

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.

Stop using Cyclogest and contact your doctor at once if you have an allergic reaction. Signs may include a skin rash, which may be itchy.

Common (may affect up to 1 in 10 people)

Drowsiness, stomach discomfort or pain, breast pain

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

Diarrhoea, soreness in your rectum (back passage), flatulence (wind), changes in your menstrual cycle (you may find that your monthly period will start earlier than usual or it may be delayed), leakage after the pessary has dissolved (this is quite normal when using medicines that are inserted into the vagina or rectum)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store

Keep this medicine out of the sight and reach of children.

Store below 25°C in a dry place.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 pessaries contain

- The active substance (the ingredient that makes the medicine work) is progesterone. Each pessary contains 200mg of the active ingredient.
- The other ingredients are vegetable fat.

What Progesterone pessaries looks like and contents of the pack

Progesterone pessaries are off-white pessaries.

Pack sizes are 15.

Marketing Authorisation Holder

Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland.

Manufacturer

Accord-UK Limited, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom

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Further Information:

Premenstrual Syndrome

Many women suffer from a condition called premenstrual syndrome or PMS. This is commonly known as PMT (premenstrual tension) because of the anxiety and bad temper often associated with it. However, there are many other symptoms that occur with PMS including depression, bloating and breast tenderness. It is not just your symptoms that decide whether you have PMS but the time at which they are at their worst.

PMS is characterised by the symptoms that occur during the days leading up to your period and are then completely relieved by menstruation. The cause of PMS is not completely understood but it is believed to be related to the hormonal changes that occur during the monthly cycle. Many women obtain relief from their symptoms when their hormonal balance is altered with a medicine prescribed by their doctor.

Further information about PMS can be obtained from:

National Association for Premenstrual Syndrome
41 Old Road
East Peckham
Kent
TN12 5AP

Post-Natal Depression

Many mothers experience short-term periods of mild depression following the birth of their baby. This is a common condition, usually occurring three or four days after delivery, affecting at least half of all new mothers who may feel tearful, overwhelmed and irritable during this time. Support, reassurance and rest can help these feelings to pass within a few days.

However, if the anxiety does not improve, the mother may be developing postnatal depression. Up to 15 per cent of new mothers develop more severe symptoms within 12 months of their child's birth. Postnatal depression (PND) is characterised by marked low mood for a more prolonged period of time.

Though it may take several weeks or months until a full recovery is reached, PND is a treatable condition from which the mother will get better.

Speak to your midwife, health visitor or doctor if you have any further questions.