What Cyclogest is and what it is used for
Cyclogest contains micronised progesterone which is a natural, female sex hormone, produced in the body. Cyclogest 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.

What you need to know before you use Cyclogest
Do not use Cyclogest 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.

How to use Cyclogest
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.

Warnings and precautions
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 Cyclogest if you have or ever have had:
- liver problems such as jaundice (yellowing of the skin and whites of the eyes)
- epilepsy
- asthma
- cardiac or renal dysfunction
- diabetes

Children
There is no relevant use of Cyclogest in children.

Other medicines and Cyclogest
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 Cyclogest 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.

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

Packaging and storage
Store below 25°C.

Contents of the pack and other information
- 1 pessary
- Inactive ingredients: cellulose, hypromellose, talc, titanium dioxide, stearic acid.
- A pessary may also contain: dextrin, sodium chloride, sodium lauryl sulfate.
You should insert Cyclogest into the:
- **vagina** if you have:
  - coils (inflammation of the column causing frequent attacks of diarrhoea with mucus 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 hard fat from the pessary.

For premenstrual tension start using Cyclogest 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 Cyclogest.

### How to insert Cyclogest

To insert into the:
- **Vagina** - place the pessary between the lips of the vagina and push the pessary upwards and backwards. You may feel 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 Cyclogest 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 Cyclogest

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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 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)

- 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 or via the Yellow Card app, which can be downloaded from the Apple App Store, or Google Play Store.

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

### How to store Cyclogest

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

Do not store above 30°C.

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.

### Contents of the pack and other information

**What Cyclogest contains**

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

**What Cyclogest looks like and contents of the pack**

Cyclogest are off-white, torpedo-shaped pessaries. Pack sizes are 15.

**Marketing Authorization Holder**

L.D. Collins & Co. Ltd.

1st Floor, Gallery Court, 28 Arcadia Avenue, London, N3 2FG, UK.

**Manufacturer**

Accord UK Ltd., Burnstaple, EX32 8NS, UK.

This leaflet was last revised in March 2022.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**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.