



Product Information Insert

Company's name:

Actavis, Barnstaple, EX32 8NS, UK

1. **Identification**
 - 1.1 **Trade name:** CYCLOGEST®
 - 1.2 **Generic name:** Progesterone.
- 2./3. **Form and strengths:** Pessaries each containing 200mg and 400mg progesterone.
4. **Pharmaco-therapeutic group:** Progesterone is a progestational steroid.
5. **The name and address of the manufacturing authorisation holder**
Actavis, Barnstaple, EX32 8NS, UK
6. **Therapeutic indications**
 - 1) Treatment of premenstrual syndrome, including premenstrual tension and depression.
 - 2) Treatment of puerperal depression.
7. **Active and inactive ingredients and their quantities**
Each pessary contains as active ingredient 200mg and 400mg progesterone.
Inactive ingredient: Vegetable fat.
8. **A list of information**
 - 9.2 **In pregnant women**
Due to the indications of the product, unless advised by the treating physician, it is anticipated that it will not be administered to pregnant women. As progesterone is a natural hormone, it is not expected to have adverse effects, however, no evidence is available to this effect.
 - 9.3 **In breast feeding women**
As progesterone is a natural hormone, it is not expected to have adverse effects, however, no evidence is available to this effect.
 - 9.4 **In the elderly**
Not applicable.
 - 9.5 **Persons with specific pathological conditions**
Progesterone is metabolised in the liver and should be used with caution in patients with hepatic dysfunction.
 - 9.6 **Potential effects on the ability to drive and use machines**
None known.
 - 9.7 **Details of excipients**
None.
 - 9.8 **Council of Arab Health Ministers warning**
- 8.1 **Contra-indications**
Undiagnosed vaginal bleeding.
- 8.2 **Precautions**
Use vaginally if patients suffer from colitis or faecal incontinence. Use rectally if patients suffer from vaginal infection (especially moniliasis) or recurrent cystitis. Use rectally in patients who have recently given birth. Use rectally if barrier methods of contraception are used.
Progesterone is metabolised in the liver and should be used with caution in patients with hepatic dysfunction.
Cyclogest contains the hormone progesterone which is present in significant concentrations in women during the second half of the menstrual cycle and during pregnancy. This should be borne in mind when treating patients with conditions that may be hormone-sensitive.
- 8.3 **Drug and food interactions**
None known.
9. **Special warnings**
 - 9.1 **In children**
Not applicable.
10. **Instructions for proper use**
 - 10.1 **Dosage**
Adults: 200mg daily to 400mg twice a day, by vaginal or rectal insertion. For premenstrual syndrome commence treatment on day 14 of menstrual cycle and continue treatment until onset of menstruation. If symptoms are present at ovulation commence treatment on day 12.
 - 10.2 **The method and route of administration**
For rectal or vaginal insertion.
 - 10.3 **Duration of treatment**
Individually, see point 10.1 above.
 - 10.4 **Overdose**
There is a wide margin of safety with Cyclogest pessaries, but overdosage may produce euphoria or dysmenorrhoea.
 - 10.5 **Action to be taken when one or more doses have not been taken**
The patient should continue the treatment as prescribed.
 - 10.6 **Indication – the risk of withdrawal effects**
None.
11. **Undesirable effects**
Menstruation may occur earlier than expected, or, more rarely, menstruation may be delayed. Soreness, diarrhoea and flatulence may occur with rectal administration.
As with other vaginal and rectal preparations, some leakage of the pessary base may occur.
12. **Reference to the expiry date:**
36 months from the date of manufacture.
13. **Storage conditions:** Store below 25°C in a dry place.
14. **Warning against visible signs of deterioration:** Do not use the medicine.
15. **Date of last revision of the insert:**
May 2007.

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.