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CYCLOGEST® 200 MG, 400 MG PESSARIES

Actavis

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 200 mg and 400 mg 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 200 mg and 400 mg progesterone.

Inactive ingredient: Vegetable fat.

8. A list of information

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.

9.2 In pregnant women
Due to the indications of the product, 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.

10. Instructions for proper use

10.1 Dosage
Adults: 200 mg daily to 400 mg 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:
September 2001.