

Section 3 - Summary of Product Characteristics

Product Summary

1 Trade Name of the Medicinal Product

CYCLOGEST 200mg

2 Qualitative and Quantitative Composition

Each pessary contains 200mg Progesterone PhEur.

3 Pharmaceutical Form

Off-white pessaries.

Clinical Particulars

4.1 Therapeutic Indications

- 1) Treatment of premenstrual syndrome, including premenstrual tension and depression.
- 2) Treatment of puerperal depression.

4.2 Posology and Method of Administration

Posology

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.

Children: Not applicable.

Elderly: Not applicable.

Method of Administration

For rectal or vaginal insertion.

4.3 Contraindications

Undiagnosed vaginal bleeding.

4.4 Special Warnings and Precautions for Use

Use rectally if barrier methods of contraception are used.

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.

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.

4.5 Interactions with other Medicaments and other forms of Interaction

None known.

4.6 Pregnancy and Lactation

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.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 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.

4.9 Overdose

There is a wide margin of safety with Cyclogest pessaries, but overdosage may produce euphoria or dysmenorrhoea.

Pharmacological Properties

5.1 Pharmacodynamic properties

ATC code: G03D A

Progesterone is a progestational steroid.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

Pharmaceutical Particulars

6.1 List of excipients

Also contains: vegetable fat.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life

Three years from the date of manufacture.

Shelf-life after dilution/reconstitution

Not applicable.

Shelf-life after first opening

Not applicable.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

The product may be supplied in strip packs contained in cartons:

Carton: White backed folding box board printed on white.

Strip pack: Aluminium foil lacquer-laminated to 20µm polypropylene foil and coated on the reverse with polythene (20mg/m²). The alternative is thermoplastic film and laminated PVC to 95µm and polyethylene to 27-30µm.

Pack sizes: 5s, 12s, 15s

6.6 Instructions for use/handling

Not applicable.

Administrative Data

7 MARKETING AUTHORISATION HOLDER

Actavis UK Limited
(Trading style: Actavis)
Whiddon Valley
Barnstaple
North Devon
EX32 8NS

United Kingdom

8 Marketing Authorisation Number

PL 00142/0507

9 Date of First Authorisation/Renewal of Authorisation

23 August 2000

10 DATE OF REVISION OF THE TEXT

February 2007