

Gesta®

200 mg, 400 mg Pessaries

IDENTIFICATION

Trade name: Gesta®

Generic name: Progesterone

Form and strengths: Pessaries each containing 200mg and 400mg progesterone.

Excipient: Suppocire BS2.

PHARMACO-THERAPEUTIC GROUP:

Progesterone is a progestational steroid.

THERAPEUTIC INDICATIONS:

- 1) Treatment of premenstrual syndrome, including premenstrual tension and depression.
- 2) Treatment of puerperal depression.
- 3) Indicated for the supplementation of insufficient secretion of progesterone in women participating in fertilization programs.

ACTIVE AND INACTIVE INGREDIENTS AND THEIR QUANTITIES:

Each pessary contains as active ingredient 200 mg and 400mg progesterone.

Inactive ingredient: Vegetable fat.

A LIST OF INFORMATION

CONTRA-INDICATIONS:

Undiagnosed vaginal bleeding.

PRECAUTIONS:

Use vaginally if patients suffer from colitis or faecal incontinence.

Progesterone is metabolized in the liver and should be used with caution in patients with hepatic dysfunction. Gesta® 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.

DRUG AND FOOD INTERACTIONS:

None known

SPECIAL WARNINGS:

IN CHILDREN

Not applicable.

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.

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.

IN THE ELDERLY

Not applicable

PERSONS WITH SPECIFIC PATHOLOGICAL CONDITIONS:

Progesterone is metabolized in the liver and should be used with caution in patients with hepatic dysfunction

POTENTIAL EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES

None known.

DETAILS OF EXCIPIENTS

None

INSTRUCTIONS FOR PROPER USE

DOSAGE

Adult: 200 mg daily to 400mg twice a day, by vaginal 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.

For fertilization support purposes 200mg inserted into the vagina daily but can be increased to 400mg twice daily.

THE METHOD AND ROUTE OF ADMINISTRATION

For vaginal insertion.

DURATION OF TREATMENT

Individually, see the dosage

OVERDOSE

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

ACTION TO BE TAKEN WHEN ONE OR MORE DOSES HAVE NOT BEEN TAKEN:

The patient should continue the treatment as prescribed.

INDICATION-THE RISK OF WITHDRAWAL EFFECTS:

None

UNDESIRABLE EFFECTS:

Menstruation may occur earlier than expected, or, more rarely menstruation may be delayed.

As with other vaginal preparations, some leakage of the pessary base may occur.

STORAGE CONDITIONS:

Store below 25°C in dry place.

WARNING AGAINST VISIBLE SIGNS OF DETERIORATION:

Do not use the medicine.

PRESENTATION:

Pessaries:

Gesta® 200 mg / 15 Pessaries

Gesta® 200 mg / 30 Pessaries

Gesta® 400 mg / 15 Pessaries

Gesta® 400 mg / 30 Pessaries

This is a medicament:

- A medicament is a product that 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 experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep out of reach of children.

*Council of Arab Health Ministers
Union of Arab Pharmacists*



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