

Microgest[®]

(Natural Micronised Progesterone)

Softgel capsule –100mg/200mg

COMPOSITION:

Each Microgest[®] soft gelatin capsule contains: Progesterone BP 100 mg/200mg

PHARMACOLOGY:

Microgest[®] softgel capsule contains micronised progesterone, which is structurally and biologically identical to natural endogenous progesterone. Micronisation increases the bioavailability of progesterone. When micronised progesterone is administered after meals, maximal serum progesterone levels are significantly increased. Progesterone concentrations in the endometrial and breast tissue attain high level. Progesterone is approximately 96%-99% bound to serum proteins, primarily to serum albumin (50%-54%). Progesterone is metabolized to pregnanediols and pregnanones in the liver. The glucuronide and sulfate conjugates of pregnanediol and pregnanone are excreted in the bile and urine. Progesterone metabolites, which are excreted in bile, may undergo enterohepatic circulation.

INDICATIONS

1. Maintenance of Pregnancy in cases of Threatened / Recurrent abortion.
2. Luteal support during IUI and ART procedures IVF-ET.
3. Luteal support in cases of proven luteal phase insufficiency.
4. Along with estrogen in post-menopausal hormone replacement therapy (HRT) either in sequential or in continuous regimen.
5. To prevent endometrial hyperplasia where endogenous estrogen is present.
6. As progesterone challenge test in secondary amenorrhoea.
7. For cycle control along with estrogen therapy.
8. Dysfunctional uterine bleeding (DUB)
9. Premenstrual tension.
10. Endometriosis.
11. Oocyte donation programme.
12. Benign mastopathy.

DOSAGE AND ADMINISTRATION

The usual recommended dose: Microgest[®] 100mg/200mg 2 to 3 softgel capsules daily by the oral or vaginal routes in divided doses. Flexible dosage regimen can be followed depending on the indication and requirements of patients.

• **Maintenance of Pregnancy in cases of Threatened / Recurrent abortion:** Microgest[®] 200 to 400 mg per day in divided doses.

• **In-vitro fertilization and embryo transfer :** Microgest[®] 200mg thrice a day from the day of embryo transfer till pregnancy is confirmed. If pregnant, it is continued till 12th week of pregnancy.

• **HRT :** In sequential regimen: Microgest[®] 200mg daily for 12 days in last 2 weeks of each therapeutic cycle. In continuous regimen: Microgest[®] 100 mg daily throughout the month along with estrogen.

• **Oocyte donation programme :** Microgest[®] 100mg twice daily from the day of transfer till pregnancy is confirmed. This may be increased to a maximum of 600 mg per day and continued till 12th week of pregnancy.

• **Luteal support :** Microgest[®] 100mg thrice a day from the 17th day of the cycle for 10 days in induced cycle. If pregnant, it is continued till 12th week of pregnancy.

• **Luteal phase insufficiency:** Microgest[®] 100mg thrice daily to be continued up to 12 weeks of pregnancy, increasing the dose by 100mg/day/week to a maximum of 600mg/day in divided doses if required.

• **In secondary amenorrhoea:** Microgest[®] 300mg for 10 days results in withdrawal bleeding in 80% of cases.

• **Premenstrual syndrome:** Microgest[®] 100-200mg daily for 10 days from 17th to 26th day of each menstrual cycle.

• **Benign mastopathy:** Microgest[®] 200-300 mg for 10 days per month, usually from 17th to 26th day of the monthly cycle.

PRECAUTIONS:

Severe renal insufficiency, diabetes mellitus, seizures, migraine, headache, heart diseases, depression.

CONTRAINDICATIONS:

Hypersensitivity, hepatic dysfunction, undiagnosed vaginal bleeding, porphyria, cancers of uterus and genital organs, breast cancers, history of stroke or blood clots. It should not be used in a case of miscarriage and tissue left in the uterus.

DRUG INTERACTION:

Ketoconazole inhibits the metabolism of progesterone.

ADVERSE EFFECTS:

Microgest[®] is devoid of estrogenic, androgenic and mineralocorticoid effects. Mild somnolence and other CNS side effects like depression, breast tenderness and bloating are reported. Side effects are less when vaginal route is used.

STORAGE:

Keep in a cool, dry and dark place.

PRESENTATION:

Microgest[®] 100 mg: Blister of 10's, pack of 3x10's.

Microgest[®] 200 mg: Blister of 10's, Pack of 3x10's.