

Mygest

Progesterone (Micronized) USP 100mg & 200mg Soft Capsule

For Oral / Vaginal use

Composition : Mygest 100 : Each Soft Gelatin Capsule Contains Progesterone (Micronized) USP 100mg.

Mygest 200 : Each Soft Gelatin Capsule Contains Progesterone (Micronized) USP 200mg.

Pharmacology : Mygest softgel capsule contains micronized progesterone, which is structurally and biologically identical to natural endogenous progesterone. Micronisation increases the bioavailability of progesterone. When micronized 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 pregnanolones in the liver. The glucuronide and sulfate conjugates of pregnanediol and pregnanolone are excreted in the bile and urine. Progesterone metabolites, which are excreted in bile, may undergo enterohepatic circulation.

Indication : Progesterone softgel capsule is indicated in- 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 & Administration : The usual recommended dose: Progesterone 100mg/200mg 2 to 3 soft gel 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:** Progesterone 200 to 400mg per day in divided doses. **In-vitro fertilization and embryo transfer:** Progesterone 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: Progesterone 200mg daily for 12 days in last 2 weeks of each therapeutic cycle. In continuous regimen: Progesterone 100mg daily throughout the month along with estrogen. **Oocyte donation programme:** Progesterone 100mg twice daily from the day of transfer till pregnancy is confirmed. This may be increased to a maximum of 600mg per day and continued till 12th week of pregnancy. **Luteal support:** Progesterone 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:** Progesterone 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:** Progesterone 300mg for 10 days results in withdrawal bleeding in 80% of cases. **Premenstrual syndrome:** Progesterone 100-200mg daily for 10 days from 17th to 26th day of each menstrual cycle. **Benign mastopathy:** Progesterone 200-300mg for 10 days per month, usually from 17th to 26th day of the monthly cycle. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with 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.

Precautions : Caution should be exercised when it is using in patients with severe renal insufficiency, diabetes mellitus, migraine, seizures, headache, heart diseases, depression.

Side effects : Progesterone 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.

Use in pregnancy & lactation : Pregnancy category B. Caution should be exercised when Progesterone Capsules are administered to a nursing woman.

Use in Child : There is no data available.

Drug Interactions : Ketoconazole inhibits the metabolism of progesterone.

Overdose : There is no data available.

Storage : Store below 30^o C in a dry place.

Packing : Mygest 100 : Each box contains 30's Capsule in blister pack.

Mygest 200 : Each box contains 30's Capsule in blister pack.

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh