H = 300 mm
W = 130 mm

Progel

Gel

Progesterone Micronized USP

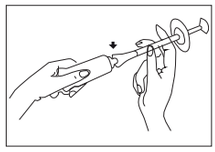
Composition
Each gram vaginal gel contains Progesterone Micronized USP 80 mg.

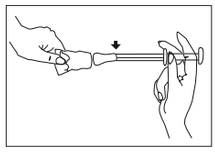
Pharmacology
Progel contains micronized Progesterone which is structurally and biologically identical to natural endogenous progesterone. Progesterone is secreted by the ovary, placenta, and adrenal gland. In the presence of adequate estrogen, progesterone transforms a proliferative endometrium into a secretory endometrium. Progesterone is necessary to increase endometrial receptivity for implantation of an embryo. Once an embryo is implanted, progesterone acts to maintain the pregnancy. Progesterone administration decreases the circulatory levels of gonadotropins.

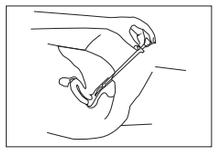
Indication
Maintenance of pregnancy in case of Threatened/Recurrent abortion. Luteal support during IVF and ART. Luteal support in case of proven luteal phase insufficiency. Secondary Amenorrhea. Dysfunctional Uterine Bleeding (DUB).

Dosage and administration
Route of administration: Vaginal application
Maintenance of pregnancy in case of Threatened/Recurrent abortion: Use Progel vaginally once daily (90 mg of 8% gel). Reproductive failure and in vitro fertilization treatment: Progel is given at a dose of 90 mg. Treatment is started within 4 days, preferably 2 days, after hCG (human chorionic gonadotropin) administration. One application of Progel 90 mg (8% gel) should be given vaginally daily or twice daily. Most women will respond to 90 mg given daily. However, some women may need 90 mg twice daily. If pregnancy occurs treatment may continue for up to 10 to 12 weeks.
Secondary Amenorrhea: Use Progel once a day (90 mg of 8% gel) for every alternative day for 6 days.
OR AS DIRECTED BY THE PHYSICIAN.

How to apply the Gel :
One application (applicator used to the ring mark) contains 1.125 gm of Progel, which contains 90 mg progesterone.







1. Remove cap from the tube, invert it, and use the sharp point to open the tube.
2. Pull the plunger up to the ring. Now attach it to the opening of the tube.
3. Squeeze the tube slowly to the applicator up to the ring-mark (where the plunger stops).
4. Remove the tube.
5. To apply the Gel, lie down; insert the applicator deep into the vagina.
6. Slowly push the plunger all the way in until the applicator is empty.
7. After use, pull the plunger out of the barrel beyond the point of resistance and wash both parts in warm, soapy water. Do not use detergents. Rinse well and dry afterwards. Do not put the applicator in hot or boiling water.

Contraindication
Known or suspected malignancy of the breast or genital organs, Missed abortion, Undiagnosed uterine bleeding, Liver dysfunction or disease, Known hypersensitivity to any of the components of the formulation, Known or suspected progesterone-dependent neoplasia, Active thrombophlebitis or thromboembolic disorders, cerebral apoplexy, or a history of hormone associated thrombophlebitis or thromboembolic disorders, Acute porphyria.

Warning and precaution
If cerebrovascular disorders, pulmonary embolism, and retinal thrombosis occurs, the drug should be discontinued immediately. Treatment should be discontinued if the results of liver function tests become abnormal or if cholestatic jaundice appears. Patients with a history of depression should be carefully observed and discontinue the drug if the depression recurs to a serious degree. Progel should not be used concurrently with other vaginal therapy.

Side effects
***Common side effects*:** Abdominal pain, perineal pain, constipation, nausea, Diarrhea, vomiting, breast enlargement, dyspareunia, depression, decreased libido, nervousness, and somnolence, intermenstrual bleeding (spotting), vaginal irritation.
***Rare side effects*:** cerebrovascular disorders, pulmonary embolism.

Use in pregnancy & lactation
Pregnancy category A. It has been used to successfully support embryo implantation and maintain pregnancies. Do not use during lactation. Detectable amounts of progestogens have been identified in the milk of mothers receiving them. The effect of this on the nursing infant has not been determined.

Use in children and adolescents
Progel is not indicated for use in children.

Drug interaction
With medicine: Although no interactions with other drugs have been reported, Progel is not recommended for use concurrently with other vaginal preparations.
With food & others : No interaction

Overdose
Acute over dosage is unlikely with this product due to the concentration-dependent, rate-limited absorption of progesterone by the vaginal epithelium and the prolonged release characteristics of the formulation. However, in case of over dosage, discontinue Progel and treat the patient symptomatically.

Storage
Store below 25^0 C temperature & dry place, protected from light.
Keep all medicines out of reach of children.

Packing
Each pack has lami tube contains 22.5 gm vaginal gel with dedicated applicator.

***Further information is available on request**

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Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness