



PROGEST
100 mg or 200 mg
Soft Gelatin Capsules
For Oral or Vaginal Use

L. Ver. 3

Composition : Each soft gelatin capsule contains : Active ingredient : Progesterone (micronized) 100 mg or 200 mg.
Inactive ingredients : Pasmul Oil, Soyalecithin.
Shell : For Progest 100 mg : Glycerin, Glycol, Sodium ethyl hydroxybenzoate, Sodium propyl hydroxybenzoate, Titanium dioxide powder, Cochineal red, FD & C yellow.
For Progest 200 mg : Gelatin, Glycerol, Sodium ethyl hydroxybenzoate, Sodium propyl hydroxybenzoate, Titanium dioxide powder.

Therapeutic Indications - Oral :
Disorders related to progesterone deficiency, in particular :

- Pre-menstrual syndrome,
- Menstrual irregularities by dysovulation or anovulation,
- Benign mastopathies,
- Premenopausal,
- Replacement therapy for menopause (in addition to estrogen therapy).

Vaginally :

- Substitution of progesterone in the ovarian failure or complete deficits ovary deprived woman (oocyte donation).
- Supplementation of the luteal phase during in vitro fertilization cycles (IVF).
- Supplementation of the luteal phase during spontaneous or induced cycles, in case of hypofertility or primary or secondary sterility, in particular by dysovulation.
- In case of treated abortion or provocation of repeated abortions due to luteal insufficiency until the 12th week of pregnancy.
- In all other indications, the vaginal use represents an alternative to the oral route in case of side effects due to progesterone (drowsiness after oral absorption).

Dosage and method of administration : In all therapeutic indications, it is important to strictly follow the recommended dosages.

Whatever the indication and route of administration (oral or vaginal), the dose should not exceed 200 mg per day.

Oral use : In deficiencies of progesterone, the average dose is 200 to 300 mg of micronized progesterone per day.

It is recommended to use the product between meals, preferably in the evening at bedtime.

In the luteal insufficiency : (premenstrual syndrome, benign mastopathies, menstrual irregularities, premenopause), the usual regimen is 200 mg to 300 mg daily per day taken as 200 mg at bedtime or 300 mg in 2 doses, 10 days per cycle, usually from 17th to 29th day.

In replacement therapy for menopause, the estrogen therapy alone is not recommended (risk of endometrial hyperplasia) : add progesterone at 200 mg daily in two doses of 100 mg each, at bedtime for 10 to 14 days per month, or the last 2 weeks of each therapeutic sequence.

This treatment will be followed by an interruption of any substitution therapy for about one week, during which it is usual to observe a deprivation in hemorrhage.

In these indications, use the vaginal route, at the same dosages as the oral route, in cases of side effects due to progesterone (somnolence after oral absorption).

Vaginal use : Each capsule should be inserted deep into the vagina.

Progesterone substitution in the ovarian deficiencies or complete deficits ovary deprived women (oocyte donation) :

The regimen (in addition to an appropriate estrogen therapy) is as follows :

- 100 mg of micronized progesterone per day from the day 13th and 14th day of the transfer cycle then 200 mg of micronized progesterone per day from the 15th to 25th day of the cycle, divided into two doses per day and from 26th day of the cycle and in case of early pregnancy, this dose may be up to 600 mg/ divided into 2 doses.
- The dosage will be continued until the 60th day, and until the 12th week of pregnancy.
- Supplementation of the luteal phase during IVF cycles :
- Supplementation of the luteal phase during spontaneous or induced cycles, in cases of hypofertility or primary or secondary sterility, in particular dysovulation: the recommended dosage is 200 mg to 300 mg per day from 17th day of the cycle for 10 days. The treatment should be quickly repeated in the absence of amenorrhea and diagnosis of pregnancy until the 12th week of pregnancy.

Early treated abortion or provocation of repeated abortions due to luteal insufficiency : the recommended dosage is 200 to 400 mg daily in two divided doses, up to the 12th week of pregnancy.

Contraindications : This medicine is contraindicated in patients with severe changes in liver function.

Special Warnings and precautions :

Warnings :

- More than half of early spontaneous abortions are due to genetic complications. In addition, infectious

phenomena and mechanical disorders may be responsible for early abortions. The only effect of administering progesterone would be to delay the ejection of the dead egg (or the interruption of a non-progressive pregnancy).

- The use of progesterone should be restricted to cases in which secretion of corpus luteum is insufficient.
- Treatment in the conditions of use, is not a contraceptive.
- The use of Progest (100 & 200 mg) should only be used in pregnancy during the first trimester and by vaginal use. Progest (100 & 200 mg) is not a treatment of preterm labor.
- Cases of hepatocellular liver disease and in cases of cholestasis in pregnancy were exceptionally reported with administration of micronized progesterone during the 2nd and 3rd trimesters of pregnancy.

Interactions with other drugs and other forms of interaction :
Not applicable.

Pregnancy and breast feeding : Numerous epidemiological studies involving more than a thousand patients did not find any relationship between progesterone and fetal malformations.

Effects on ability to drive and use machines : Progest (100 & 200 mg) may cause drowsiness or dizziness. Therefore, caution should be taken when driving or using machines when taken this medicine by mouth.

Side effects :

Oral :

- Drowsiness or transient dizziness, occurring 1-3 hours after intake of the product. In that case, decrease the dose, or change the timing of administration.
- (for example, 200 mg / day, take 200 mg at bedtime in a single dose, away from time of meals) or take the medicine by vaginal route.
- Shortening of the menstrual cycle or breakthrough bleeding may occur.
- If this occurs, start treatment later in the cycle (eg. start from 19th day of the cycle instead of 17th). These effects occur more often with an overdose.

Vaginally :

- No local intolerance (burning, itching, or greasy flow) was observed during the various clinical studies.
- No common side effect, especially drowsiness or dizziness, have been reported in clinical studies at the recommended dosage.

Pharmacological Properties :
Pharmacodynamic properties : Progesterone.
Properties of Progest are comparable to those of natural progesterone, in particular : gestagen, antiestrogen, low androgenic, anti-androgenic.

Pharmacokinetic properties :

Oral use :

Absorption :
Micronized progesterone is absorbed via the digestive tract. The rise in progesterone begins from the first hour and the highest plasma levels are observed 1 – 3 hours after the intake. Pharmacokinetic studies carried out in volunteers showed that after the simultaneous ingestion of two capsules of 100 mg progesterone, progesterone in blood ranges from 0.13 ng / ml to 4.25 ng / ml after 1 hour, 11.75 ng / ml at 2 hours, 6.37 ng / ml at 4 hours, 2 ng / ml at 6 hours and 1.64 ng / ml at 8 hours. Taking into account the tissue retention time of the hormone, it is necessary to divide the dose into two applications, about 12 hours between one another, in order to achieve an appropriate throughout all day. There are sensitive individual variations, however the same individual retains the same pharmacokinetic characteristics to several months apart, enabling individual adaptation of the dosage.

Metabolism : In plasma, the main metabolites are 4, 4-dihydroprogesterone and 6-dihydroprogesterone. Urinary excretion is 95% in the form of glucuronide conjugate metabolites, the main of which is 3 α, 5 β, pregnanediol (pregnanediol). These plasma and urinary metabolites are identical to those found in the physiological secretion of the ovarian corpus luteum.

Vaginally :

Absorption : After vaginal insertion, the absorption of progesterone by the vaginal mucosa is rapid, since high plasma levels of progesterone are observed within the first hour after application. The maximum plasma concentration of progesterone is reached within 5 – 8 hours after the application and is maintained at a 24 - hour mean concentration of 5.7 ng / ml after administration of 100 mg morning and evening. This average recommended dosage therefore induces physiological and stable plasma progesterone concentrations, similar to those observed during the luteal phase of menstrual cycle. The small inter-individual variations in progesterone levels make it possible to precisely predict the expected effect with a standard dosage.

At doses higher than 200 mg / day, the progesterone concentrations obtained are comparable to those described during the first trimester of pregnancy.

Metabolism : In plasma, the concentration 5 β - progesterone is not increased. Urinary excretion is mainly in the form of 3 α, 5 β - pregnanediol (pregnanediol) as evidenced by the progressive increase of its concentration (up to the maximum concentration of 142 ng / ml at the 6th hour).

Packing :

For Progest 100 mg : A carton box containing two (2) colorless transparent PVC / strips, each of 12 soft gelatin capsules and an inner pamphlet.

For Progest 200 mg : A carton box containing two (2) colorless transparent PVC / strips, each of 15 soft gelatin capsules and an inner pamphlet.

Storage : Store at temperature not exceeding 30° C, in a dry place.

Keep out of the reach of children.

Manufactured by : Technopharma Egypt
For : Pharco Pharmaceuticals
Issue date 01/03/2023

PROGEST L. Ver. 3
100 mg or 200 mg
Pamphlet code **TMP1101**
Pharmacode serial No.: **2030**

Dimensions: **16 cm *16 cm**
Prepared by: **Mohamed Elsokary**
Update : **01 /01 / 2023**
Update : **27 /02 / 2023**

Update : **28 /08 / 2023**