PACKAGE LEAFLET:
Information for the patient

PROGESTERON

Solution for injection - 25 mg / 1 ml

(Progesterone)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. WHAT PROGESTERON IS AND WHAT IT IS USED FOR

Progesterone is secreted by the corpus luteum of the ovaries during the second phase of the menstrual cycle (luteal phase), and also from placenta during pregnancy. LH stimulates the secretion of this hormone through cAMP.
At the end of the cycle, the abrupt reduction of the secretion of progesterone causes menstruations.
Progesterone is necessary for the maintenance of pregnancy.
Under the action of progesterone, the temperature of the body increases with about 0.5°C.
Progesterone acts in the development of the mammary glands during pregnancy and for a minor development during the luteal phase.
Progesterone has little estrogenic and androgenic properties.

It is indicated in:

- dysfunctional uterine bleeding;
- amenorrhea.

Your doctor may have given Progesteron for another purpose. Ask your doctor if you want to know why you have been given this drug.

2. BEFORE YOU TAKE PROGESTERON

Do not take Progesteron if you:

- are hypersensitive to the drug or to any of the other excipients of the solution for injection;
- have severe hepatic failure or chronic or acute hepatic diseases;
- have vaginal bleeding with an undiagnosed origin;
- have diagnosed or history of tumours of the liver;
- have cholestatic jaundice;
- have hormone - dependent cancer;
- have thrombophlebitis, thromboembolic disorders, cerebral vascular accidents;
- suffer from severe depressions;
- have a history of ectopic pregnancy;
- are pregnant or suspect for pregnancy;
- are during lactation.

If you think that you have any of the above-mentioned conditions, do not take the drug. Talk initially to your doctor and follow the given advices.

Take special care with Progesteron

Progesterone should be carefully used in asthma, migraine, epilepsy, cardiac or renal failure or in other conditions also, that would be aggravated by water retention.
Also, care should be taken in patients with hypercholesterolemia and in those in whom jaundice, recurring pruritus or herpes has appeared during pregnancy.
In diabetic patients the glycemic level should be monitored because of the risk of damage of glucose tolerance that may increase the need to adjust the hypoglycemiant treatment.
If suddenly visual disorders or migraine attack appear, before the treatment continues, ophtalmological controls must be made to avoid papillary oedema or vascular lesions.
After the use of progestins (and estrogenics), benign alterations and more rarely malign alterations of the liver have been observed, which in isolated cases have developed hemorrhage, hepatomegaly or intra - abdominal hemorrhage. In this case, a liver tumour should be taken into consideration until the differential diagnosis is made, and if necessary, the treatment should be stopped.

Cases when treatment should be interrupted:

- the first symptoms of thromboemboly or thrombophlebitis appear (the first occurrence of severe or highly frequent headache of migraine type, abrupt visual disturbs, brutal hearing loss, thorax pain and pressure, deep vein thrombosis, thrombophlebitis, cerebrovascular disturbs, pulmonary oedema, coronary occlusion);
- generalized pruritus, abnormal hepatic parameters, cholestatic jaundice, hepatomegaly with the suspicion of a liver tumour appear;
- there is an abrupt increase of the arterial pressure;
- severe depression appears for the first time or it is repeated;
- surgical intervention is planned, the treatment should be stopped 6 weeks before;
- the patient is pregnant.

The patient should be informed that the risk for thromboembolic accident increases from smoking, overweight, advanced age, hypertension, coagulation disorders, aggravated diabetes, varicous veins and also from thrombosis and treatment of venous diseases.

Taking other medicines

Enzymatic inducers (barbiturates and other anticonvulsants, rifampicin, griseofulvin) increase the metabolism of progesterone, reducing its efficacy.
Some antibiotics (eg. ampicillin and tetracyclines) may reduce the efficacy of progestins by affecting the intestinal flora.
Smoking may decrease the bioavailability of progesterone, while alcohol abuse may increase it.
Ask for the advice of the doctor or pharmacist if you are concomitantly taking Progesteron with the above mentioned drugs.

Taking Progesteron with food and drinks

Smoking may reduce the bioavailability of progesterone while alcohol abuse may increase it.

Pregnancy

Category D.
Inform your doctor or pharmacist if you are pregnant or you are planning to get pregnant, because this drug is **contraindicated** in pregnancy.
Positive evidences for risk in the human foetus (eg. virilisation in the female foetus) exist. Because of this risk and in the absence of an indication, pregnancy should be definitely excluded before treatment begins. During treatment, an effective contraceptive method should be used.

Breast - feeding

Inform your doctor or pharmacist if you breastfeed the baby with breast milk, because this drug is **contraindicated** during breast - feeding.
Progesterone passes in small amounts in breast milk. It inhibits lactation. The effects in the neonate are not known.
Breast - feeding should be stopped if the treatment with progesterone is necessary.

Driving and using machines

Progesteron may cause dizziness and drowsiness, therefore care should be taken during the use of this medicine.

3. HOW TO TAKE PROGESTERON

Before the beginning of the treatment, a medical examination is necessary to avoid any tumour of the genital tract or of the breast. Also, pregnancy should be excluded. In case of long - term treatment, these controls should be made every 6 - 12 months.

Progesteron should be used only in females of reproductive age.

Amenorrhea

5 - 10 mg i.m. daily, for 6 - 8 days. The treatment should be initiated 8 - 10 days before the expected menstruations.
If the function of the ovaries is sufficient, menstruations occur 48 - 72 hours after the treatment is stopped.
In some patients, a single cycle of treatment is necessary to set a regular menstrual cycle, but generally, many treatment cycles are required.

Abnormal uterine bleeding

5 - 10 mg i.m. daily, 5 - 10 days before the expected onset of menstruations, or a single injection of 50 - 100 mg.
The treatment should be repeated every month to obtain a regular menstrual cycle.

If you take more Progesteron than you should

If you take more Progesteron or if the children have taken this drug by mistake, please contact your doctor, hospital, or call the emergency to take an opinion for the risk and advice for the actions to be taken.

If you forget to take Progesteron

If you forget a dose, take the following dose when it is time to take the usual dose.
Do not take a double dose to make up for the forgotten dose.

If you have any other questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All drugs may cause side effects. Sometimes they are serious, most of the time not.
Progesterone may cause:

- in the skin: pain and oedema in the site of injection, in some cases urticaria, pruritus, rush, acne, chloasma, increased pilosity;
- in the genital tract: frequent disorders of the menstrual cycle, amenorrhea with spots, mammary tension, galactorrhea, reduced libido, increased vaginal secretions, hystological changes in the ovaries and in the uterus, also virilisation;
- in the CNS: sometimes headache, dizziness, drowsiness or insomnia, nervous agitation, depressive condition;
- in the digestive tract: sometimes nausea, oedema, in case of high doses it causes a transitory increase of the excretion of sodium and chloride, change of lipid profile, change of glucose tolerance;
- in the blood: rarely it causes an increase of the coagulation factors VII, VIII, IX and X.

Benzyl alcohol which is present in the solution may cause hypersensitivity reactions.
Inform your doctor if any of the above - mentioned side effects affects you.
If you notice adverse effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE PROGESTERON

Keep out of the reach and sight of children.
Do not use Progesteron after the expiry date which is stated on the package.
Store below 25°C.

6. OTHER INFORMATION

What Progesteron contains

The active substance is Progesterone.
Each ampoule of 1 ml contains 25 mg progesterone.
The other excipients are: benzyl alcohol, ethyl oleate.

Content of the pack

Carton box with 10 ampoules.
Carton box with 100 ampoules (hospital use).

Explanatory of the illustration icons on the packaging:


According to medical prescription.


Content.


Warning.


Solution for injection.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in December 2014.

SPECIFICATION

CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.