

PATIENT INFORMATION

PROGESTERONE INJECTION USP

For Intramuscular Use Only

FOR THE TREATMENT OF AMENORRHEA (ABSENCE OF MENSES IN WOMEN WHO HAVE PREVIOUSLY HAD A MENSTRUAL PERIOD) OR ABNORMAL UTERINE BLEEDING DUE TO HORMONAL IMBALANCE.

Please read this information carefully before you start to use Progesterone Injection and each time your prescription is renewed, in case anything has changed. This leaflet does not take the place of discussions with your doctor. If you still have any questions, ask your doctor or health-care provider.

About Progesterone Injection

Progesterone Injection is a sterile injectable solution containing the natural female hormone called progesterone. Progesterone Injection is indicated for the treatment of amenorrhea and abnormal uterine bleeding due to progesterone deficiency.

Understanding the role of Progesterone Injection in the treatment of your menstrual irregularities.

Progesterone is one of the hormones essential for regular menstrual periods. If your doctor has determined your body does not produce enough progesterone on its own, Progesterone Injection may be prescribed to provide the progesterone you need.

When you do not produce enough progesterone, menstrual irregularities can occur. Progesterone Injection can provide you with the progesterone needed during a normal menstrual cycle.

Possible side effects of Progesterone Injection

The following side effects have been reported with Progesterone Injection. Consult your doctor if you experience any of the side effects mentioned below, or other side effects.

- breakthrough bleeding
- spotting
- changes in menstrual flow
- amenorrhea
- change in weight (increase or decrease)
- pain, irritation, swelling, and/or redness at the injection area
- general swelling
- vaginal discharge
- yellow discoloration of skin or white of eyes
- breast tenderness, discharge from the nipple
- skin reactions including rash, hives, itching, and swelling
- acne

- hair loss or growth of new hair
- mental depression
- fever
- insomnia or sleepiness*
- nausea
- anaphylactoid (life-threatening allergic) reaction with symptoms that may include a sense of uneasiness or apprehension; flushing; fast, throbbing heartbeat; itching; hives; difficult breathing; swelling of the throat; fainting; nausea; vomiting; or convulsions.

*If you experience sleepiness, do not drive or operate machinery.

When you should not use Progesterone Injection

- If you are allergic to progesterone, progesterone-like drugs, benzyl alcohol or sesame oil/seeds.
- If you have unusual vaginal bleeding which has not been evaluated by your doctor.
- If you have liver disease.
- If you have known or suspected cancer of the breast or genital organs.
- If you have a miscarriage and your physician suspects some tissue is still in the uterus.
- If you have or have had blood clots in the legs, lungs, eyes, or elsewhere.

Risks of Progesterone Injection

- Abnormal blood clotting. Blood clots have been reported with the use of estrogens and progestational drugs (alone or in combination). If blood clots do form in your bloodstream, they can cut off the blood supply to vital organs, causing serious problems. These problems may include a stroke (by cutting off blood to part of the brain), a heart attack (by cutting off blood to part of the heart), a pulmonary embolus (by cutting off blood to part of the lungs), or other problems. Any of these conditions may cause death or serious long-term disability. Call your doctor immediately if you suspect you have any of these conditions. He or she may advise you to stop using this drug.

Precautions

Be alert for unusual signs and symptoms. If any of these warning signals (or any other unusual symptoms) happen while you are using Progesterone Injection, call your doctor immediately:

- Abnormal bleeding from the vagina.
- Pains in the calves or chest, a sudden shortness of breath or coughing blood indicating possible clots in the legs, heart, or lungs.
- Severe headache or vomiting, dizziness, faintness, or changes in vision or speech,

- weakness or numbness of an arm or leg indicating possible clots in the brain or eye.
- Breast lumps, which could be associated with fibrocystic disorders, fibroadenoma, or breast cancer. (Ask your doctor or health-care provider to show you how to examine your breasts monthly.)
 - Yellowing of the skin and/or white of the eyes indicating possible liver problems.

How Progesterone Injection works

Progesterone Injection is intended for administration by injection into a muscle mass. Following injection, the medication is absorbed into the bloodstream.

Other information

1. Your doctor has prescribed this drug for you and you alone. Do not give this drug to anyone else.
2. This medication was prescribed for your particular medical condition. Do not use it for another condition.
3. Keep this and all drugs out of the reach of children.

How to use Progesterone Injection

Progesterone Injection will be administered to you by a health-care provider or your caregiver. Your doctor will provide instructions regarding the dose and manner in which the medication should be injected. Follow your doctor's instructions closely. If you have any questions about product administration, ask your doctor or health-care provider.

How Supplied

Progesterone Injection, 50 mg/mL is available in 10 mL multiple dose vials. Vials are individually boxed.

Progesterone Injection should be stored at controlled room temperature 15-30°C (59-86°F).

Do not use Progesterone Injection after the expiration date which is printed on the vial label.

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