

PROGESTERONE INJECTION

This is a compounded medication that must be stored between 59-86 degrees F. Progesterone in oil should be a clear solution, but if it is stored below 59 degrees F, and perhaps depending on altitude, the progesterone MAY COME OUT OF SOLUTION and clump into gel like or particle like formations. If this happens do not fret, you may heat the solution to 120-150 degrees Fahrenheit in order to bring the progesterone back into solution. Please allow the product to cool to room temperature and ensure that it is clear before injecting. We will not replace medication vials that have been improperly stored and therefore have come out of solution. Please find a warm, dry place to store your medication. If you normally lower your thermostat during the day, please find an appropriate storage place for your progesterone vials that is maintained in the necessary temperature range.

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from heat and light. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. The FDA classifies compounded progesterone as a hazardous medication (although commercially available product is not classified as such in spite of being the same active ingredient). Properly discard this product when it is expired or no longer needed in a sharps container or according to the regulations of your city or state. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

USES

Progesterone is a type of female hormone (progestin). This medication is similar to the progesterone that your body naturally makes. It is given to replace the hormone when your body is not making enough of it, including during ART. In women who are not pregnant and have not gone through menopause, this medication is used to restore normal menstrual periods that have stopped for several months (amenorrhea). It is also used to treat abnormal bleeding from the uterus that is due to low hormone levels and not due to other causes (e.g., fibroids, cancer of the uterus). Progesterone must not be used to test for pregnancy. Progestins are not effective in preventing miscarriages.

HOW TO USE

Read the Patient Information Leaflet provided by your pharmacist before you start using progesterone and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Inject this medication into a muscle, usually once daily or as directed by your doctor. This medication is usually given for 6 to 12 weeks (fertility patients). Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid and refer to paragraph 1 or call the pharmacy. Dosage is based on your medical condition and response to treatment. Before injecting each dose, clean the injection site with rubbing alcohol. It is important to change the location of the injection site daily to avoid problem areas in the muscle. Use this medication regularly to get the most benefit from it. To help you remember, use it at the same time each day. Tell your doctor if your condition persists or worsens.

SIDE EFFECTS

Pain/swelling at injection site, breast tenderness, headache, weight gain/loss, acne, nausea, increased body/facial hair, loss of scalp hair, drowsiness, or dizziness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: unusual vaginal bleeding/discharge (e.g., breakthrough bleeding, spotting), stopped menstrual periods (amenorrhea), breast lumps, swelling of the ankles/feet, mental/mood changes (e.g., depressions, nervousness), dark patches on the skin/face, frequent/painful urination, dark urine, yellowing eyes/skin, stomach/abdominal pain, persistent nausea/vomiting. This drug may rarely cause blood clots. Seek immediate medical attention if any of these rare but very serious side effects occur: chest/jaw/left arm pain, weakness on one side of the body, slurred speech, vision changes (e.g. blurred/double vision, loss of vision), confusion, pain/redness/swelling of arms or legs, trouble breathing, sudden severe headache, fainting. A very serious allergic reaction to this drug is rare. However, seek immediate medication attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before using progesterone, tell your doctor or pharmacist if you are allergic to it; or to any oil; or if you have any other allergies. This product may contain other inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: history of blood clots, history of bleeding in the brain, liver, disease, and cancer of the breast or other female organs, vaginal bleeding of unknown cause, a loss of pregnancy with some tissue remaining in the uterus (“missed abortion”).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: migraine headaches, seizures, asthma, heart disease (e.g., coronary artery disease, congestion, depression, diabetes, high blood levels of cholesterol/triglycerides). This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. If you will be having surgery or will be confined to a chair or bed for a long time (e.g., a long plane flight), tell your doctor beforehand. Special precautions may be needed. Do not smoke. Smoking combined with this medication further increases your risk for strokes, blood clots, high blood pressure, and heart attacks. If you have diabetes, this product may make it harder to control your blood sugar levels. Check your blood sugar levels regularly as directed by your doctor. Tell your doctor immediately if you have symptoms of high blood sugar, such as increased thirst and urination. Your anti-diabetic medication or diet may need to be adjusted. This medication may cause blotchy, dark areas on your skin (melasma). Sunlight may worsen this effect. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen, and wear protective clothing when outdoors.

DRUG INTERACTIONS

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor or pharmacist first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs affecting liver enzymes that remove progesterone from your body (such as azole antifungals including itraconazole, rifamycins including rifabutin, St. John’s wort, certain anti-seizure medicines including carbamazepine/phenytoin). This medication may interfere with certain laboratory tests, possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES

Do not share this medication with others. Keep all appointments with your doctor and the laboratory. You should have a complete physical examination that includes blood pressure measurements and breast/pelvic examinations at regular intervals (e.g., once a year) or as directed by your doctor. Follow your doctor’s instructions on how to examine your own breasts and report any lumps immediately. You should also be regularly screened for cervical cancer (e.g. Pap test) and have periodic mammograms as determined by your doctor. Consult your doctor for more details.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule.

USING MULTIPLE NEEDLES TO DRAW UP OR INJECT

Some physicians will prescribe one needle to draw up medication and another to inject medication. While this is a preference on the part of the physician, please be advised that whenever a needle is used medication will be left inside the barrel of the syringe. Some needle sizes will contain as much as 0.2ml of medication so although the vials are overfilled with progesterone solution, depending on the sizes of the needles the vial may not provide enough doses due to waste.

PROGESTERONE SUPPOSITORIES, CREAMS OR TROCHES

Storage: Store at room temperature between 59-86 degrees F (15-30 degrees C) away from heat and light.

SIDE EFFECTS

Same as above. Patients experience fewer side effects with this route of administration. The drug is absorbed locally.