

Package leaflet: Information for the user

Progesterone 25 mg solution for injection progesterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Progesterone is and what it is used for
2. What you need to know before you use Progesterone
3. How to use Progesterone
4. Possible side effects
5. How to store Progesterone
6. Contents of the pack and other information

1. What Progesterone is and what it is used for

This medicinal product contains the active ingredient progesterone. Progesterone is a naturally occurring female sex hormone. It works on the lining of the womb and helps you to become pregnant and to stay pregnant.

The treatment is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) programme who are unable to use or tolerate vaginal preparations.

2. What you need to know before you use Progesterone

Do not use Progesterone

- If you are allergic to progesterone or any of the other ingredients of this medicine (listed in section 6).
- If you are suffering from vaginal bleeding (other than normal periods) that has not been evaluated by your doctor
- If you have a miscarriage and your doctor suspects some tissue is still in the womb
- If you currently have a pregnancy outside of the womb (ectopic pregnancy)
- If you currently have or have had severe liver problems
- If you have known or suspected breast cancer or cancer of the reproductive tract
- If you have or have had blood clots in the legs, lungs, eyes or elsewhere in the body
- If you have porphyria disorders (a group of inherited or acquired disorders of certain enzymes)
- If during pregnancy you have suffered from jaundice (yellowing of eyes and skin due to liver problems) severe itching and/or blisters on the skin
- If you are under 18 years of age.

Warnings and precautions

Take special care with this medicine

If you experience any of the following during treatment **tell your doctor immediately** as your treatment may need to be stopped. Also tell your doctor immediately if you experience these a few days after the last dosage:

- Heart attack (pains in the chest, or back pain and/or deep aching and throbbing in one or both arms, a sudden shortness of breath, sweating, dizziness, lightheadedness, nausea, palpitations)
- Stroke (severe headache or vomiting, dizziness, faintness, or changes in vision or speech, weakness or numbness of an arm or leg.)
- Blood clots in the eyes or anywhere in the body (pain in your eyes or pain and swelling in your ankles, feet and hands)
- Worsening of depression
- Severe headaches, changes in vision.

Before treatment with this medicine

Tell your doctor if you have had or have any of the following before using Progesterone:

- Liver problems (mild or moderate)
- Epilepsy
- Migraine
- Asthma
- Heart or kidney problems
- Diabetes
- Depression

If any of the above applies to you, your doctor will monitor you carefully during treatment.

Children and adolescents

The product is not to be used by children or adolescents.

Other medicines and Progesterone

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Including medicines obtained without a prescription and herbal medicines. Some medicines may interact with this medicinal product. For example:

- Carbamazepine (used to treat seizures/fits)
- Rifampicin (an antibiotic)
- Griseofulvin (an antifungal medicine)
- Phenytoin and Phenobarbital (used to treat epilepsy)
- St. John's Wort-containing herbal products.
- Ciclosporine (a medicine for some types of inflammation and after organ transplants)
- Diabetic medicines.
- Ketoconazole (an antifungal medicines)

Do not administer Progesterone at the same time as any other injectable medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- This treatment can be used during the first three months of pregnancy.
- This medicine should not be used during breast-feeding.

Driving and using machines

Do not drive or use any tools or machines if you feel drowsy and/or dizzy whilst taking this medicine.

3. How to use Progesterone

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Remember this treatment should only be used under the supervision of a doctor experienced in treating fertility problems

The recommended dose is a once daily injection of 25 mg usually until 12 weeks of confirmed pregnancy (i.e. 10 weeks of treatment).

How Progesterone should be given

The solution for injection can be given either under your skin (subcutaneous injection) or into a muscle (intramuscular injection).

You will be able to administer 25 mg of this medicine subcutaneously after suitable advice and training by your doctor or healthcare professional.

Subcutaneous injection:

Before you inject the solution you will receive the following training and advice:

- Practice giving subcutaneous injections
- Where to inject your medicine
- How to prepare your solution for injection
- How to administer your medicine.

Please read instruction below on preparation and administration of this medicine.

The steps for self-administration are:

- A Preparing your injection
- B Checking pack
- C Preparing the vial and syringe
- D Filling the syringe
- E Changing the injecting needle
- F Removing air bubbles
- G Injection by subcutaneous administration
- H Disposal of used items.

These steps are explained in full below.

IMPORTANT: each vial should only be used once. The solutions should be used immediately after opening the vial. It should not be stored in the syringe.

A. Preparing your injection

It is important to keep everything as clean as possible, so start by washing your hands thoroughly and drying on a clean towel. Choose a clean area to prepare your medicine:

- One vial containing the solution for injection

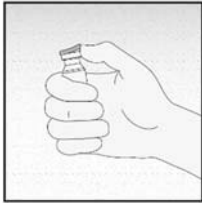
The following items are not supplied with your medicine. Your doctor or pharmacist will supply these items.

- One syringe
- One large needle (typically 21G green needle; for intramuscular administration)
- One small fine needle (typically 27G grey needle; for subcutaneous injection)
- Two alcohol wipes
- A sharps container (for safe disposal of needles, vials etc.)

B. Checking pack

- The solution vial, syringe and needles all have protective covers.
- Check that all the covers are on firmly and if they are not on properly or are damaged, do not use them.
- Make sure that the expiry date is still valid on the vial of the solution for injection. Do not use the products if outside the expiry date.

C. Preparing the vial and syringe

	• Remove the plastic cap from the top of a the vial containing the solution by gently pushing it upwards. • Wipe the rubber top with an alcohol wipe and allow to dry • Unpack the syringe, hold the syringe • Take the packaging off the large 21G green needle, but keep the needle cover on • Hold the syringe in your hand, attach the large 21G green needle to the syringe, then remove the needle cover
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D. Filling the syringe

	• Push the large 21G green needle through the middle of the rubber vial top • With the needle still inserted, turn the vial upside down. The needle should support the vial unaided • Make sure the large needle tip is underneath the level of the liquid • Gently pull the plunger to draw all the mixture into the syringe • Pull the large needle out of the vial.
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E. Changing the injecting needle

This step is only required if you are doing a subcutaneous administration; if your doctor is performing an intramuscular injection they will move on to set the dose and administer the injection.

- Put the needle cover on the large 21G green needle and then gently take the large needle off the syringe
- Remove the smaller 27G grey injecting needle, from its package, keeping the needle cover on
- Attach the small 27G grey needle onto the syringe then remove the needle cover.

F. Removing air bubbles

	• Holding the syringe straight up with the small 27G grey needle pointing to the ceiling, draw back slightly on the plunger and tap the syringe so that any air bubbles rise to the top. • Slowly press the plunger until all the air is out of the syringe and at least one drop of solution comes out of the tip of the small 27G grey needle
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G. Injection by subcutaneous administration

- Your doctor or healthcare professional will have already shown you where to inject this medicine (e.g. tummy or front of thigh)
- Open the alcohol wipe and carefully clean the area of skin to be injected, and allow it to dry
- Hold the syringe in one hand. Use the other hand to gently pinch the skin in the injection site area between your thumb and index finger

	• Using a dart-like motion insert the fine grade small 27G grey needle into the skin so the skin and needle form a right angle.
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- Insert the small 27G grey needle all the way into the skin. **Do not inject directly into a vein**

- Inject the solution by pushing gently on the plunger in a slow and steady motion until all the solution is injected beneath the skin. Inject all of the prescribed solution
- Release the skin and pull the needle straight out
- Wipe the skin at the injection site with an alcohol swab using a circular motion.

H. Disposal of used items

- Once you have finished your injection, put all needles, empty vials and syringes into a sharps container.
- Any unused solution must also be thrown away.

Injection by intramuscular administration should be given only by a doctor or healthcare professional

For all intramuscular injections, your doctor or another healthcare professional will perform the injection.

The injection will be given into the side of the thigh or bottom. Your doctor or healthcare professional will clean the area of skin to be injected using an alcohol wipe and allow it to dry. Using a dart-like motion they will insert the large needle into the muscle. They will inject the solution by pushing gently on the plunger in a slow and steady motion until all the solution is injected into the muscle. They will pull the needle straight out and wipe the skin at the injection site with an alcohol wipe.

If you use more solution than you should

Tell your doctor or pharmacist. The symptoms of an overdose include drowsiness.

If you forget to use Progesterone

Do not take a double dose to make up for a forgotten dose.

Take the dose as soon as you remember and then carry on as before. Tell your doctor what you have done.

If you stop using Progesterone

Do not stop the treatment without speaking to your doctor or pharmacists first. Abrupt discontinuation of this medicine may cause increased anxiety, moodiness, and increase your risk of having seizures (fits).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and seek immediate medical help if you have any of the following symptoms:

- Overstimulation of the ovaries (symptoms include lower stomach pain, feeling thirsty and sick, and sometimes being sick, passing reduced quantities of concentrated urine and weight gain),
- Depression,
- Yellowing of your skin and the whites of your eyes (jaundice),
- Severe allergic reaction which may cause difficulty breathing, swelling of the face and throat or a severe rash (anaphylactoid reactions).

Very common: may affect more than 1 in 10 people

- Pain, redness, itching, irritation or swelling at the injection site
- Uterine spasm
- Vaginal bleeding.

Common: may affect up to 1 in 10 people

- Headache

- Bloating stomach
- Stomach pain
- Constipation
- Being sick and feeling sick
- Breast tenderness and/or pain
- Vaginal discharge
- A tingling or uneasy irritation or itching of the skin of the vagina and the surrounding area
- Hardening of area around injection site
- Bruising around injection site
- Fatigue (excessive tiredness, exhaustion, lethargy).

Uncommon: may affect up to 1 in 100 people

- Changes in mood
- Dizziness
- Insomnia
- Stomach and intestinal disturbance (including stomach discomfort and/or tenderness, wind, painful spasms and retching)
- Skin rashes (including red warm skin, or raised, itchy bumps or wheals or dry, cracked or blistered or swollen skin)
- Breast swelling and/or enlargement
- Feeling hot
- General feeling of discomfort or “feeling out of sorts”
- Pain.

Not known: frequency cannot be estimated from the available data

The following disorders, although not reported by patients in clinical studies using Progesterone, have been described with other progestins: inability to sleep (insomnia), premenstrual like syndrome and menstrual disturbances, hives, acne, excessive hair growth, hair loss (alopecia), weight gain.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA

Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Progesterone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Do not refrigerate or freeze. Store in the original package in order to protect from light.

Do not use this medicine if you notice particles in the solution or if the solution is not clear. This medicinal product must be used immediately after first opening. Any remaining solution must be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What this solution for injection contains

- The active substance is progesterone. Each vial of 1.112 mL contains 25 mg progesterone (22.48 mg/mL).
- The other ingredients are hydroxypropylbetadex and water for injections.

What Progesterone looks like and contents of the pack

Clear, colourless to light brown solution, practically free from visible particles supplied in a colourless glass vial.

Each pack contains 1, 7 or 14 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

Manufacturer

Laboratorios Farmalán, S.A.
Calle La Vallina, s/n, Edificio 2,
Polígono Industrial Navatejera
24193- Villaquilambre, León, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Fergesten 25 mg, Injektionslösung
Denmark	Progesteron Exeltis
Estonia	Lutavia 25 mg süstelahus
Germany	Fergesten 25 mg, Injektionslösung
Hungary	Progesterone Exeltis 25 mg oldatos injekció
Ireland	Progesterone 25 mg solution for injection
Latvia	Lutavia 25 mg šķīdums injekcijām
Lithuania	Lutavia 25 mg injekcinis tirpalas
Poland	Fergesten
Slovakia	Progestanella Exeltis 25 mg, injekčný roztok
Spain	Fergesten 25 mg, solución inyectable EFG

This leaflet was last revised in May 2026.