

Package leaflet: Information for the user

Lubion 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 symptoms 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.
- Lubion 25mg solution for injection will be known as Lubion throughout this leaflet.

What is in this leaflet:

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

1. What Lubion is and what it is used for

Lubion contains the active ingredient Progesterone. Progesterone is a naturally occurring female sex hormone. The medicine works on the lining of the womb and helps you to become pregnant and to stay pregnant.

Lubion 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 Lubion

Do not use Lubion

- If you are allergic (hypersensitive) to progesterone or any of the other ingredients of Lubion
- 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 Lubion

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 Lubion

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

- 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 Lubion

Please 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 Lubion. 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 medicine)

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

- Lubion 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 Lubion.

Lubion contains hydroxypropylbetadex

If you have a kidney disease, talk to your doctor before you receive this medicine.

Lubion contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to use Lubion

Always use Lubion exactly as your doctor has told you. Remember Lubion should only be used under the supervision of a doctor experienced in treating fertility problems.

How much Lubion should you use and for how long?

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

How Lubion should be given

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

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

Subcutaneous injection:

Before you inject Lubion 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 Lubion.

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 Lubion 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.)

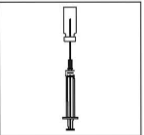
B. Checking pack

- The Lubion 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 Lubion. 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 Lubion vial 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

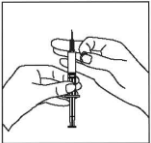
	• Push the large 21G green needle through the rubber middle of the Lubion vial top • With the needle still inserted, turn the vial upside down. The needle should support the vial unaided • Make sure the large needle tip is underneath the level of the liquid • Gently pull the plunger to draw all the mixture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

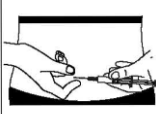
- Put the needle cover on the large 21G green needle and then gently take the large needle off the syringe
- Remove the smaller 27G grey injecting needle, from its package, keeping the needle cover on
- Attach the small 27G grey needle onto the syringe then remove the needle cover.

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 Lubion (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 given only by a doctor or healthcare professional

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

The Lubion 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 Lubion than you should

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

If you forget to use Lubion

Take the dose as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose. Tell your doctor what you have done.

If you stop using Lubion

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

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

4. Possible side effects

Like all medicines, Lubion 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 Lubion , 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lubion

Keep out of the sight and reach of children.

Store below 25°C.

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

This medicinal product must be used immediately after first opening.

Any remaining solution must be discarded.

Do not use Lubion after the expiry date which is stated on the label after Exp:

If the expiry date is reported as month/year, the expiry date refers to the last day of that month.

Do not use Lubion if you notice particles in the solution or if the solution is not clear.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lubion contains

The active substance is Progesterone. Each vial (1.112 ml) contains 25 mg progesterone (theoretical concentration 22.48 mg/ml).

The other ingredients are: Hydroxypropylbetadex, Disodium phosphate, Sodium dihydrogen phosphate dihydrate, Water for injections

What Lubion looks like and contents of the pack

Lubion is a clear colourless solution supplied in a colourless glass vial.

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

Marketing Authorisation Holder

IBSA Farmaceutici Italia Srl
Via Martiri di Cefalonia, 2
26900 Lodi (Italy)

Manufacturer:

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Via Martiri di Cefalonia, 2
26900 Lodi – Italy

IBSA Pharma Limited (for UK)
Units 4-6 Colonial Business Park, Colonial Way
Watford WD24 4PR
United Kingdom

This medicinal product is authorized in the Member States of the EEA under the following names: (The strength and pharmaceutical form are identical in all countries, only the trade name changes)

Austria: Progedex
Belgium: Inprosub
Bulgaria: Prolutex
Cyprus: Prolutex
Czech Republic: Prolutex
Denmark: Prolutex
Estonia: Lubion
Finland: Prolutex
France: Progiron
Germany: Prolutex
Greece: Prolutex
Hungary: Prolutex
Italy: Pleyris
Lithuania: Lubion
Latvia: Lubion
Luxembourg: Inprosub
Norway: Prolutex
Poland: Prolutex
Portugal: Prolutex
Romania: Prolutex
Slovakia: Prolutex
Sweden: Prolutex
Spain: Prolutex
The Netherlands: Prolutex
United Kingdom: Lubion

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder via medinfo.uk@ibsagroup.com