Package leaflet: Information for the user

Lubion 25 mg solution for injection in pre-filled syringe

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 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.

What you need to know before you use Lubion
Do not use Lubion
- 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 currently 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 medicines)

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

2. How to use Lubion

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. 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 recommended 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
Lubionshould be given under your skin (subcutaneous injection, i.e. SC).

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

Before you inject Lubion you will receive the following training and advice:
- Practice giving subcutaneous injections.
- Where to inject your medicine.
- 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 Injection
D Disposal of used items.

These steps are explained in full below.

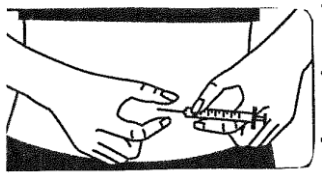
A. Preparing your injection
It is important to keep everything as clean as possible, so start by washing your hands thoroughly and drying on a clean towel. Choose a clean area to prepare your injection.

The following items are **not** supplied with your medicine. Your doctor or pharmacist will supply these items.
- Two alcohol wipes
- A sharps container (for safe disposal of pre-filled syringe etc.)

B. Checking pack
- Do not use the product if the packaging is open or damaged.
- Make sure that the pre-filled syringe of Lubion contains the solution.
- Make sure that the expiry date is still valid on the pre-filled syringe of Lubion. Do not use the products if outside the expiry date.

C. Injection
- 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.
- Remove the cap. Once the cap is removed, do not allow the needle to touch anything. This is to make sure the needle remains clean (sterile).

- Hold the syringe with the needle pointing upwards and 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 needle.
- 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 needle into the skin so that the skin and the needle form a right angle.

- Insert the 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 the 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.

Each pre-filled syringe is for single-use only.

D. Disposal of used items
- Once you have finished your injection, put the pre-filled syringe into a sharps container.

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 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
- Bloated 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 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
- Drowsiness
- 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 HPRA Pharmacovigilance www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lubion

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

Do not refrigerate or freeze.
Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and pre-filled syringe label after EXP.
Do not use this medicine if you notice particles in the solution or if the solution is not clear.

Each pre-filled syringe is for single-use only.

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 Lubion contains

The active substance is progesterone. Each pre-filled syringe (1.112 ml) contains 25 mg progesterone (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

Lubionis a clear colourless solution for injection in pre-filled syringe supplied in a glass syringe.

Each carton box contains 7 or 14 pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

IBSA Farmaceutici Italia S.r.l.
Via Martiri di Cefalonia 2
26900 Lodi
Italy

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

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

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