

Package leaflet: Information for the user

Lutinus® 100 mg vaginal tablets

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

1. What Lutinus is and what it is used for

This medicine is provided as a vaginal tablet that contains the natural female sex hormone progesterone.

Lutinus is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) programme.

Progesterone acts on the lining of the womb and it helps you to become and to stay pregnant when you are treated for infertility.

2. What you need to know before you use Lutinus

Lutinus can be used only in women who are undergoing infertility treatment in an Assisted Reproductive Technology (ART) programme. The treatment is started on the day of egg retrieval. Your doctor will tell you when the treatment is started.

Do not use Lutinus

- if you are allergic to progesterone or any of the other ingredients of this medicine (listed in section 6).

- if you have unusual vaginal bleeding that has not been evaluated by the doctor.
- if you have a miscarriage and your physician suspects some tissue is still in the uterus or pregnancy outside of the womb.
- if you currently have or have had severe liver problems.
- if you have known or suspected breast or genital tract cancer.
- 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).

Warnings and precautions

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even a few days after the last dosage:

- 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
- worsening symptoms of depression

Before treatment with Lutinus tell your doctor if you have had or have any of the following health problems:

- Epilepsy
- Migraine
- Asthma
- Cardiac or renal dysfunction
- Diabetes

Children

There is no relevant use of Lutinus in children.

Other medicines and Lutinus

Tell your doctor if you are using, have recently used or might use any other medicines.

Some medicines may interact with vaginal progesterone tablets. For example, carbamazepine, rifampin as well as St. John's wort-containing herbal products may decrease the effectiveness, whereas products containing ketoconazole and vaginal antifungal creams may alter the actions of progesterone.

Pregnancy and breast-feeding

Lutinus can be used during the first trimester of pregnancy for women who need extra progesterone while undergoing

treatment in an Assisted Reproductive Technology (ART) programme.

The risks of congenital (conditions present at birth) anomalies, including genital abnormalities in male or female infants, from exposure to exogenous progesterone during pregnancy have not been fully established.

This medicine should not be used during breast feeding.

Driving and using machines

Lutinus has minor or moderate influence on the ability to drive and use machines. It may cause drowsiness and/or dizziness; therefore caution is advised in drivers and users of machines.

3. How to use Lutinus

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual dose is 100 mg placed directly into your vagina three times daily starting on the day of egg retrieval. The administration of Lutinus should be continued for 30 days if pregnancy has been confirmed.

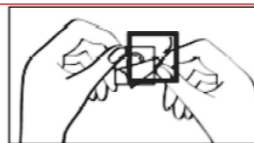
Instructions for use

Lutinus is to be placed directly into your vagina by using the applicator provided.

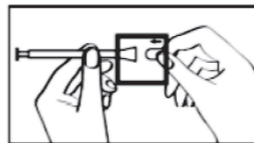
1. Remove one blister from the strip by tearing along the perforations.
2. To remove the foil seal on the back of the blister, start in the corner of the blister pack that has a printed arrow.
3. Unwrap the applicator.
4. Put one tablet in the space provided at the end of the applicator. The tablet should fit securely and not fall out.
5. The applicator with the tablet may be inserted into the vagina while you are standing, sitting, or when lying on your back with your knees bent. Gently insert the thin end of the applicator well into the vagina.
6. Push the plunger to release the tablet.

Remove the applicator and rinse it thoroughly in warm running water, wipe dry with a soft tissue and keep the applicator for subsequent use.

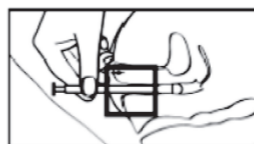
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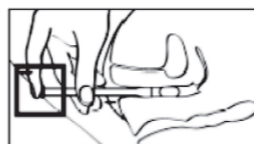
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5.



6.



If you use more Lutinus than you should

Please consult your doctor or pharmacist if you have used more Lutinus than your doctor has told you.

If you forget to use Lutinus

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.

If you stop using Lutinus

Please consult your doctor or pharmacist for advice if you intend to stop or have stopped using Lutinus. Abrupt discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensitivity to seizures.

4. Possible side effects

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

The most common side effects are headache, vaginal disorders and uterine cramping.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- Headache
- Abdominal distension (swelling in the abdomen)

- Abdominal pain
- Nausea
- Uterine cramping

The following uncommon side effects affect between 1 and 10 of every 1000 patients treated:

- Dizziness
- Insomnia
- Diarrhoea
- Constipation
- Urticaria (allergic rash)
- Rash
- Vaginal disorders (e.g. vaginal discomfort, burning sensation, discharge, dryness, and bleeding)
- Fungal infection in vagina
- Breast disorders (e.g. breast pain, breast swelling and breast tenderness)
- Itching in the genital area
- Peripheral oedema (swelling due to the build up of fluid)

The following side effects have been seen after the product was marketed. Frequency is not known (cannot be estimated from the available data):

- Fatigue
- Vomiting
- Allergic reactions

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lutinus

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. The expiry date refers to the last day of that month.

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

This medicine does not require any special temperature storage conditions.

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 Lutinus contains

The active substance is progesterone.

Each vaginal tablet contains 100 mg progesterone.

The other ingredients are:

- Hydrophobic colloidal silica
- Lactose monohydrate
- Pregelatinised maize starch
- Povidone
- Adipic acid
- Sodium hydrogen carbonate
- Sodium laurilsulfate
- Magnesium stearate

What Lutinus looks like and contents of the pack

This medicine is a vaginal tablet. It is a white to off-white convex and oblong tablet debossed with "FPI" on one side and "100" on the other side.

Pack sizes: 21 or 90 vaginal tablets, supplied with one polyethylene vaginal applicator. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ferring Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

Manufacturer

Ferring GmbH
Wittland 11, D-24109 Kiel, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Iceland, Ireland, the Netherlands, Norway, Poland, Slovak Republic, Spain and Sweden: Lutinus
Portugal: Luferti
Romania: Lutinus 100 mg, comprimate vaginale
Slovenia: Lutinus 100 mg vaginalne tablete
United Kingdom: Lutigest

This leaflet was last revised in August 2018.

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