PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LUTIGES® 100 mg vaginal tablets

Progesterone

Read all of this leaflet carefully before you start using LUTIGES®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LUTIGES® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LUTIGES® is and what it is used for

LUTIGES® is provided as a vaginal tablet that contains the natural female sex hormone progesterone.

LUTIGES® 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 helps you to become and to stay pregnant when you are treated for infertility.

2. What you need to know before you use LUTIGES®

LUTIGES® 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 LUTIGES®:

- if you are hypersensitive (allergic) to progesterone or to any of the other ingredients of LUTIGES® (listed in section 6)
- if you have unusual vaginal bleeding that has not been evaluated by the doctor
- if you ever had or think that you might have had an ectopic pregnancy (a complication of pregnancy in which the embryo attaches outside the womb) or known missed abortion (loss of pregnancy diagnosed by ultrasound or a blood test and before there is bleeding or other symptoms)
- 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 (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin).

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:

- pain 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 starting treatment with LUTIGES® tell your doctor if you have had or have any of the following health problems, your doctor may need to monitor your condition during treatment with LUTIGES®:

- epilepsy

- migraine
- asthma
- cardiac or renal dysfunction
- diabetes
- liver problems.

Children

There is no relevant use of LUTIGES® in children.

Other medicines and LUTIGES®

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines)

Some medicines may interact with vaginal progesterone tablets such as LUTIGES®. 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 as contained in LUTIGES®.

LUTIGES® is, therefore, not recommended for use with other vaginal products (such as antifungal products).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using LUTIGES® vaginal tablets.

LUTIGES® 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 such as LUTIGES®, during pregnancy has not been fully established.

LUTIGES® should not be used during breastfeeding.

Driving and using machines

LUTIGES® has minor or moderate influence on the ability to drive and use machines; it may cause drowsiness and/or dizziness.

You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which LUTIGES® affects you.

3. How to use LUTIGES®

Do not share medicines prescribed for you with any other person.

Always use LUTIGES® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 100 mg placed directly into the vagina three times daily starting on the day of egg retrieval.

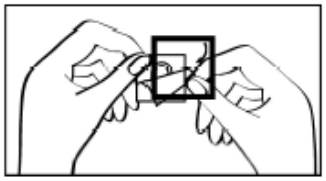
The administration of LUTIGES® should be continued for 30 days if pregnancy has been confirmed.

Your doctor will tell you how long your treatment with LUTIGES® will last. If you have the impression that the effect of LUTIGES® is too strong or too weak, tell your doctor or pharmacist.

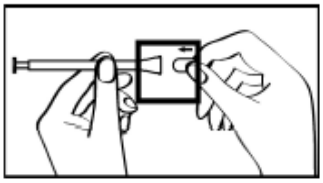
Instructions for use:

LUTIGES® is to be placed directly into the vagina using the applicator provided.

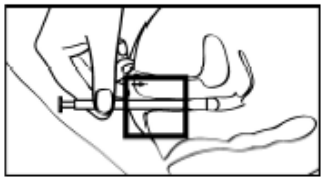
1. Remove one blister from the strip by tearing along the perforations.
2. To remove the foil seal on the back of the blister, start in the corner of the blister pack that has a printed arrow.



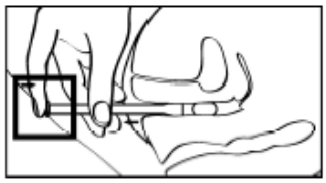
3. Unwrap the applicator.
4. Put one tablet in the space provided at the end of the applicator. The tablet should fit securely and not fall out.



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.

If you use more LUTIGES® than you should

High doses of LUTIGES® may cause drowsiness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use LUTIGES®

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 LUTIGES®

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

4. Possible side effects

LUTIGES® can have side effects.

Not all side effects reported for LUTIGES® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LUTIGES®, please consult your healthcare provider for advice.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- abdominal distension (swelling in the abdomen)
- abdominal pain
- nausea
- uterine spasm cramping felt in the uterus/womb.

Less frequent side effects:

- dizziness
- insomnia
- diarrhoea
- constipation
- urticaria (allergic rash)
- rash
- irritation or other mild reactions in or around the vagina (e.g. vaginal discomfort, burning sensation,

discharge, dryness and bleeding)

- fungal infection in the vagina
- breast disorders (e.g. breast pain, breast swelling and breast tenderness)
- itching in the genital area
- peripheral oedema (swelling due to fluid build-up).

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LUTIGES®.

To report any side effects to Ferring, please contact us on +27 12 345 6358.

5. How to store LUTIGES®

Store all medicines out of reach of children.

Store at or below 30 °C in the original container in order to protect from light.

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What LUTIGES® contains

The active substance is progesterone. Each vaginal tablet contains 100 mg progesterone.

The other ingredients are adipic acid, hydrophobic colloidal silica, lactose monohydrate, magnesium stearate, povidone, pregelatinised maize starch, sodium hydrogen carbonate, sodium lauryl sulphate.

What LUTIGES® looks like and contents of the pack

LUTIGES® are vaginal tablets. It is white to off-white convex and oblong tablets debossed with "FPI" on one side and "100" on the other side. The size of the tablet is approximately 22 mm x 13 mm.

LUTIGES® tablets are packed in Aluminium/Aluminium blisters of 3 vaginal tablets. The blisters are available in cartons with 21 or 90 vaginal tablets with one polyethylene vaginal applicator. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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