Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Endometrin
Vaginal tablets

Active ingredient - Each tablet contains 100 mg progesterone

Inactive ingredients and allergens: See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist.
Endometrin has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Endometrin is provided as a supplement or replacement of the hormone progesterone in cases of infertility and during in-vitro fertilization (IVF) treatments.

Therapeutic group:
Progestogenic hormones. Endometrin is provided as a vaginal tablet that contains the natural female sex hormone progesterone.
Progesterone acts on the lining of the womb and helps you to become and to stay pregnant when you are treated for infertility.

2. Before using this medicine

Endometrin can only be used in women who are undergoing infertility treatments. The treatment starts on the day of egg retrieval. Your doctor will tell you when to begin the treatment.

Do not use this medicine if:

- You are sensitive (allergic) to progesterone or to any of the other ingredients in this medicine (see section 6).
- You have unusual vaginal bleeding that has not been evaluated by the doctor.
- You had a miscarriage and your doctor suspects some tissue is still in the uterus or pregnancy outside of the womb.
- You currently have or have had severe liver problems.
- You have known or suspected breast or genital tract cancer.
- You have or have had blood clots in the legs, lungs, eyes or elsewhere in the body.
- You have porphyria disorders (a group of inherited or acquired disorders of certain enzymes).

Special warnings about using this medicine

Take special care and tell your doctor straight away if you experience any of these symptoms during treatment or even 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 using Endometrin, tell your doctor if you have or had any of the following health problems:
- Epilepsy
- Migraine
- Asthma
- Cardiac or renal dysfunction
- Diabetes.

Children
There is no relevant use of the medicine in children.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Carbamazepine, rifampin and preparations containing St. John's wort – may reduce effectiveness.
- Preparations that contain ketoconazole and vaginal antifungal creams may alter the actions of progesterone.

Pregnancy and breast-feeding
Endometrin 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
Endometrin 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 this medicine?

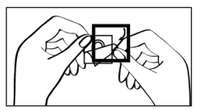
Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

100 mg placed directly into your vagina three times daily starting on the day of eggs retrieval. Use of the medicine can be continued for up to 12 weeks from the day of the retrieval.

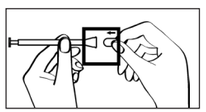
Do not exceed the recommended dose. Do not swallow the medicine!

Instructions for use
Endometrin tablet is to be placed directly into your vagina by the applicator provided with the preparation.

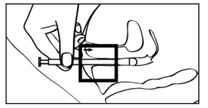
1. Wash your hands.
2. Remove the applicator from its package.



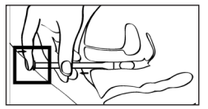
3. Put one tablet in the space provided at the end of the applicator. The tablet should fit securely and not fall out.



4. 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.



5. 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 Endometrin than you should please consult your doctor or pharmacist.

If you have taken an overdose or if a child accidentally swallowed the medicine, immediately refer to the hospital's Emergency Room and bring the package of the medicine with you.

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

Do not take the medicine in the dark! Check the label and dose every time you take the medicine. Wear glasses if you need them.
If you have any further questions about use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, Endometrin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
The most common side effects are headache, vaginal disorders and uterine cramping.

Common side effects - affect 1-10 in 100 users:
- Headache
- Abdominal distension (swelling in the abdomen)
- Abdominal pain
- Nausea
- Uterine cramping

Uncommon side effects - affect 1-10 in 1,000 users:
- 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 edema (swelling due to the buildup of fluid)

Side effects of unknown frequency (the frequency of these effects has not been established yet)
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 experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by following this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, store this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and blister tray. The expiry date refers to the last day of that month.
- Even when the medicines are stored properly, they can be stored for a limited time only. Pay attention to the expiry date of this medicine! In case of doubt, consult the pharmacist who supplied the medicine to you.
- Store below 25˚C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away this medicine. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, pregelatinized maize starch, adipic acid, sodium hydrogen carbonate, povidone, magnesium stearate, sodium lauryl sulfate, silica colloidal anhydrous

What the medicine looks like and contents of the pack:
This medicine is a rectangular off-white convex tablet with the inscriptions "FPI" on one side and "100" on the other side.
Pack sizes: 21 or 90 vaginal tablets, supplied with a polyethylene vaginal applicator to ease insertion of the tablet into the vagina.
Not all pack sizes may be marketed.

Registration holder's name and address: Ferring Pharmaceuticals Ltd., 8 Hashita st., Industrial Park Caesarea 3088900

Manufacturer's name and address:
Ferring Pharmaceuticals A/S, Denmark

This leaflet was revised in April 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 126-08-29832