

Vaginal Tablet
Progesterone (100mg)

Read the entire leaflet carefully before 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 nurse.
- 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 nurse. This includes any possible side effects not listed in the leaflet

What is in this leaflet:

1. What ENDOMETRIN is used for
2. How ENDOMETRIN works
3. Before you use ENDOMETRIN
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1. What ENDOMETRIN is used for

ENDOMETRIN is provided as a pessary (or vaginal tablet) that contains the natural female hormone, progesterone.

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

2. How ENDOMETRIN works

Each ENDOMETRIN vaginal tablet contains 100 mg of progesterone.

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

3. Before you use ENDOMETRIN®

- *Before you start to use it*

Before starting treatment with ENDOMETRIN, you and your partner should be evaluated by a doctor for the causes of your fertility problems. In particular you should be checked for the following conditions so that appropriate treatment can be given:

- Mild to moderate hepatic dysfunction
- A history of depression
- Epilepsy, migraine, asthma, cardiac or renal dysfunction
- Diabetes
- Smoking and > 35 years old

If you know you have any of the conditions listed above, please tell your doctor before starting treatment with ENDOMETRIN.

- *When not to use it*

- If you are allergic to progesterone or any of the other ingredients of ENDOMETRIN (*see Product Description*).
- If you suffer from unknown causes of vaginal bleeding
- If you have known missed abortion or ectopic pregnancy (pregnancy outside of the womb)
- If you have severe liver dysfunction or disease
- If you have known or suspected breast or genital tract cancer
- If you suffer from active arterial or venous

thromboembolism or severe thrombophlebitis, or history of these events

- If you are pregnant or breastfeeding
- If you suffer from porphyria

Talk to your doctor if you experience:

- Transient ischemic events
- Myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism (venous thromboembolism or pulmonary embolism), thrombophlebitis, or retinal thrombosis.
- Depression worsen
- Increase in fluid retention
- Appearance of sudden severe headaches
- Vision impairments related to papillary edema or retinal hemorrhage.

Tell your doctor immediately, if the symptoms develop at any time during the treatment.

Pregnancy

ENDOMETRIN vaginal tablets are only indicated during the first trimester of pregnancy for use as part of an assisted reproduction (ART) regimen.

There is yet limited and inconclusive data on the risk of congenital anomalies, including genital abnormalities in male or female infants, following intrauterine exposure during pregnancy.

Lactation

Detectable amounts of progesterone have been identified in the milk of mothers. Therefore ENDOMETRIN should not be used during lactation.

Children

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There is no relevant use of ENDOMETRIN in children.

Elderly

No clinical data have been collected in patients over age 65.

Use in special populations

There is no experience with use of ENDOMETRIN in patients with impaired liver or renal function.

If you stop using it

You might still experience increase anxiety, moodiness, and increased sensibility to seizures. Please contact your doctor immediately if any of these symptoms persist.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

ENDOMETRIN may interact with certain other medicines.

- Drugs that may lower the levels of progesterone in your blood, thus may reduce the effectiveness of ENDOMETRIN (e.g. rifampin, carbamazepine or St. John's wort (*Hypericum perforatum*)-containing herbal products)
- Drugs that may raise the levels of progesterone in your blood and hence may increase the risk for side effects (e.g. ketoconazole, erythromycin or cyclosporine)
- Concomitant use with other vaginal products has not been assessed. However, ENDOMETRIN is not recommended for use with other vaginal products (such as antifungal products) as this may alter progesterone release

and absorption from the vaginal tablet.

4. How to use ENDOMETRIN

- How much to use it

Your doctor or pharmacist will tell you how many tablets you need to use each day.

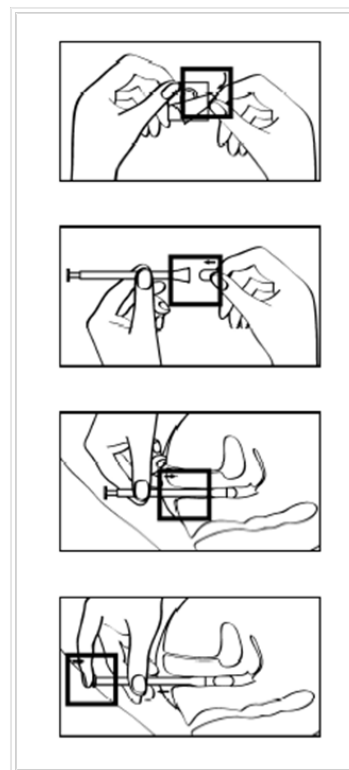
The usual dosage is one 100 mg tablet placed directly into the vagina three times daily starting on the day of egg retrieval.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

ENDOMETRIN tablets are intended to be placed directly into the vagina. An applicator is provided in the pack to help administer the tablets. Follow the directions on how to administer the tablet below:

- wash your hands thoroughly with soap and water
- unwrap the applicator and remove one vaginal tablet from the blister
- put one tablet in the space provided at the end of the applicator. The tablet should fit securely and not fall out
- 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
- 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 do not understand the instructions, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking ENDOMETRIN for as long as your doctor recommends.

- If you forget to use

ENDOMETRIN

Do not take a double dose to make up for a forgotten dose. If you are not sure what to do, talk to your doctor or pharmacist.

- If you use too much (overdose)

Please tell a nurse or doctor. High doses of progesterone may cause drowsiness. Treatment of overdosage consists of discontinuation of ENDOMETRIN together with

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institution of appropriate symptomatic and supportive care

5. While you are using it

- Things you must do

Tell any other doctors or pharmacists who are treating you that you are using ENDOMETRIN. If you are about to start taking any new medicines, tell your doctor or pharmacist that you are using ENDOMETRIN.

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 your 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.

- Things you must not do

Do not give ENDOMETRIN to anyone else, even if they have the same condition as you.

Do not use ENDOMETRIN to treat any other complaints unless your doctor has told you to.

Do not stop using ENDOMETRIN or lower the dosage, without checking with your doctor or pharmacist.

- Things to be careful of

Be careful driving or operating machinery until you know how ENDOMETRIN affects you.

Some people may experience drowsiness or dizziness. Make sure you know how you react to ENDOMETRIN before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive.

6. Side Effects

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

The following common side effects (affects between 1 to 10 of every 100 patients treated):

- Headache
- Pain in the abdomen
- Nausea
- Swelling in the abdomen
- Uterine spasm

The following uncommon side effects (affects between 1 to 100 of every 1,000 patients treated):

- Dizziness
- Insomnia
- Diarrhoea
- Constipation
- Urticaria
- Rash
- Vulvovaginal disorder (such as vulvovaginal discomfort, vaginal burning sensation, vaginal discharge, vulvovaginal dryness and vaginal haemorrhage)
- Vaginal mycosis
- Breast disorder (such as breast pain, breast swelling and breast tenderness)
- Pruritis genital
- Oedema peripheral

The following rare side effects (cannot be estimated from the available data):

- Fatigue
- Vomiting
- Hypersensitivity reactions

The above side effects were seen after ENDOMETRIN was marketed

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Report an Adverse Event)

7. Storage and disposal

Keep this medicine out of sight and reach of children.

Store in the original container. Do not store above 30°C.

Do not use ENDOMETRIN 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 medicine you no longer use. These measures will help protect the environment.

8. Product description

- What it looks like

ENDOMETRIN vaginal tablets are white to off-white convex and oblong tablets with the inscriptions "FPI" on one side and "100" on the other side.

The product is supplied as a pack of 21 vaginal tablets with 1 vaginal applicator.

- Ingredients

ENDOMETRIN®

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Active ingredient:

- progesterone.

Inactive ingredients:

- silica
- hydrophobic colloidal
- lactose monohydrate
- pregelatinized maize starch
- povidone
- adipic acid
- sodium hydrogen carbonate
- sodium lauryl sulfate
- magnesium stearate

9. Manufacturer & Product Registration Holder

Manufactured by:

Sever Pharma Solutions AB
Agneslundsvägen 27
212 15 Malmö
Sweden.

Product Registration Holder:

Ferring Sdn Bhd
21-6, Block B, Jaya One,
No. 72-A, Jalan Profesor Diraja
Ungku Aziz,
46200 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

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