

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.4)

17.1 Vaginal Bleeding

Inform patients of the importance of reporting irregular vaginal bleeding to their doctor as soon as possible.

17.2 Common Adverse Reactions with Progesterone

Inform patients of the possible side effects of progesterone therapy such as headaches, breast tenderness, bloating, mood swings, irritability, and drowsiness.

17.3 Coadministration of Vaginal Products

Inform patients that Endometrin is not recommended for use with other vaginal products.

17.4 FDA-Approved Patient Labeling

IMPORTANT: For Vaginal Use Only.

Read the patient information that comes with Endometrin before you start to use it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment. Your doctor may do a physical exam before prescribing Endometrin.

What is Endometrin?

Endometrin is a vaginal insert that contains the hormone progesterone. Endometrin is for women who need extra progesterone while undergoing treatment in an Assisted Reproductive Technology (ART) program.

Progesterone is one of the hormones essential for helping you to become and to stay pregnant. If you are undergoing ART treatment, your doctor may prescribe Endometrin to provide the progesterone your body needs.

Who should not use Endometrin?

Do not use Endometrin if you:

- Are allergic to anything in Endometrin. See the end of this leaflet for a complete list of ingredients.
- Have unusual vaginal bleeding that has not been evaluated by a doctor.
- Currently have or have had liver problems.
- Have or have had blood clots in the legs, lungs, eyes, or elsewhere in your body.

Endometrin may not be right for you. Before starting Endometrin, tell your doctor about all your health problems.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vaginal products, vitamins, herbal supplements. Some medicines may affect Endometrin.

Know what medicines you take. Keep a list of your medicines to show to the doctor and pharmacist.

How should I use Endometrin?

- Use Endometrin exactly as prescribed. The usual dose of Endometrin is one insert placed in your vagina 2 to 3 times a day for up to a total of 10 weeks, unless your healthcare provider advises otherwise.
- Place an Endometrin insert in your vagina with the disposable applicator provided.

Follow the steps below:

1. Unwrap the applicator.
2. Put one insert in the space provided at the end of the applicator. The insert should fit snugly and not fall out.
3. Place applicator with the insert into the vagina while you are standing, sitting, or when lying on your back with your knees bent. Gently place the thin end of the applicator well into the vagina.
4. Push the plunger to release the insert.
5. Remove the applicator and throw it away in the trash.

Other information for using Endometrin

- If you forget a dose of Endometrin, take the dose as soon as you remember, but do not use more than your daily dose.
- Call your doctor if you use too much Endometrin.
- Do not use any other vaginal products when you are using Endometrin.

What are the possible side effects of Endometrin?

Common side effects seen with ART and Endometrin included pelvic pain after surgery, abdominal pain, nausea, and swollen ovaries (ovarian hyperstimulation syndrome).

Other reported side effects included abdominal bloating, headache, urinary infections, uterine cramping, constipation, vomiting, tiredness, and vaginal bleeding.

Vaginal products with progesterone may also cause vaginal irritation, burning, and discharge.

Serious Risks of Progesterone

Progesterone can increase your chance of getting blood clots. Blood clots can be serious and lead to death.

Serious blood clots include those in the:

- legs (thrombophlebitis)
- lungs (pulmonary embolus)

- eyes (blindness)
- heart (heart attack)
- brain (stroke)

Call your doctor or get medical help right away if you have:

- persistent pain in the lower leg (calf)
- sudden shortness of breath
- coughing up blood
- sudden blindness, partial or complete
- severe chest pain
- sudden, severe headache, vomiting, dizziness, or fainting
- weakness in an arm or leg, or trouble speaking
- yellowing of the skin and/or white of the eyes indicating possible liver problem

Other risks of progesterone use include:

- headache
- breast tenderness
- bloating or fluid retention

- mood swings and depression
- irritability
- drowsiness

Call your doctor immediately if you have abnormal vaginal bleeding.

These are not all the side effects with Endometrin. Ask your doctor or pharmacist for more information.

How should I store Endometrin?

- Store Endometrin at room temperature, 20°- 25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)
- Do not use Endometrin after the expiration date that is printed on the carton.
- Keep Endometrin and all medicines out of the reach of children.

General information about Endometrin

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use Endometrin for a condition for which it was not prescribed. Do not give Endometrin to other women, even if they have the same condition as you do. It may harm them.

This leaflet summarizes the most important information about Endometrin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Endometrin that was written for healthcare professionals. For more information call Ferring Pharmaceuticals at 1-800-822-8214.

What are the ingredients in Endometrin?

Active Ingredient: progesterone

Inactive Ingredients: lactose monohydrate, polyvinylpyrrolidone, adipic acid, sodium bicarbonate, sodium lauryl sulfate, magnesium stearate, pregelatinized starch, and colloidal silicon dioxide

Manufactured by:

Pharmaceuticals International Inc., Hunt Valley, MD 21031

Manufactured for:

Ferring Pharmaceuticals Inc., Parsippany, NJ 07054

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