

VAGIFEM®

estradiol vaginal tablets

FDA-Approved Patient Labeling

Read this PATIENT INFORMATION before you start using Vagifem® and read what you get each time you refill your Vagifem® prescription. There may be new information. This information does not take the place of talking to your healthcare provider about your menopausal symptoms or your treatment.

What is the most important information I should know about VAGIFEM® (an estrogen hormone)

- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb)

Report any unusual vaginal bleeding right away while you are using Vagifem®. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.

- Do not use estrogen-alone to prevent heart disease, heart attacks, strokes or dementia (decline of brain function)
- Using estrogen-alone may increase your chances of getting strokes or blood clots
- Using estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age or older
- Do not use estrogens with progestins to prevent heart disease, heart attack, strokes or dementia
- Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots
- Using estrogens with progestin may increase your chance of getting dementia, based on a study of women 65 years of age or older
- You and your healthcare provider should talk regularly about whether you still need treatment with Vagifem®

What is Vagifem®?

Vagifem® is a medicine that contains estradiol (an estrogen hormone) in a vaginal tablet.

What is Vagifem® used for?

Vagifem® is used after menopause to:

- **Treat menopausal changes in and around the vagina**

You and your healthcare provider should talk regularly about whether you still need treatment with Vagifem® to control these problems.

Who should not use Vagifem®?

Do not start using Vagifem® if you:

- **Have unusual vaginal bleeding**
- **Currently have or have had certain cancers**
Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or have had cancer, talk with your healthcare provider about whether you should use Vagifem®.
- **Had a stroke or heart attack**
- **Currently have or have had blood clots**
- **Currently have or have had liver problems**
- **Have been diagnosed with a bleeding disorder**
- **Are allergic to Vagifem® or any of its ingredients**

See the list of ingredients in Vagifem® at the end of this leaflet.

- **Think you may be pregnant**

Tell your healthcare provider:

- **If you have any unusual vaginal bleeding**

Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.

- **About all of your medical problems**

Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.

- **About all the medicines you take**

This includes prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how Vagifem® works. Vagifem® may also affect how your other medicines work.

- **If you are going to have surgery or will be on bed rest**

You may need to stop using Vagifem®.

- **If you are breast feeding**

The hormone in Vagifem® can pass into your breast milk.

How should I use Vagifem®?

Vagifem® is a tablet that you place in your vagina with an applicator.

- Take the dose recommended by your healthcare provider and talk to him or her about how well that dose is working for you
- Estrogens should be used at the lowest dose possible for your treatment only as long as needed

You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about the dose you are using and whether you still need treatment with Vagifem®.

Step 1: Tear off a single applicator.

Step 2: Separate the plastic wrap and remove the applicator from the plastic wrap as shown in Figure A. If after opening the package you see that the tablet has come out of the applicator but has not fallen out of the package, carefully put it back into the applicator for insertion. Please keep your hands clean and dry while handling the tablet.

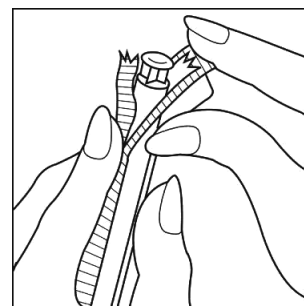


Figure A

Step 3: Hold the applicator so that the finger of one hand can press the applicator plunger as shown in Figure B.

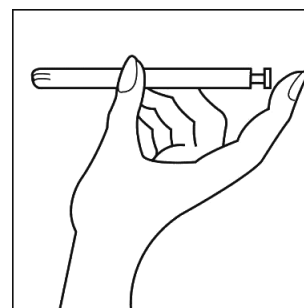


Figure B

Step 4: Next select the best position for vaginal insertion of Vagifem® (estradiol vaginal tablets) that is most comfortable for you. See suggested reclining Figure C or standing Figure D position illustrated below:

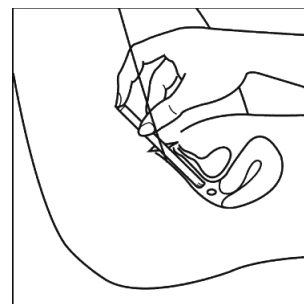


Figure C

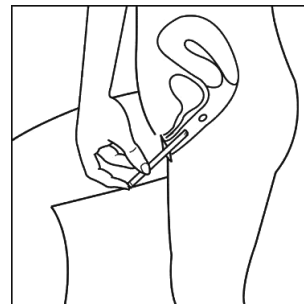


Figure D

Step 5: Using the other hand, guide the applicator gently and comfortably through the vaginal opening (see Figures C and D above). If prior to insertion the tablet falls out of the

applicator, throw the tablet and applicator away and use a new tablet-filled applicator.

Step 6: The applicator should be inserted (without forcing) as far as comfortably possible, or until half of the applicator is inside your vagina, whichever is less.

Step 7: Once the tablet-filled applicator has been inserted, gently press the plunger until the plunger is fully depressed. This will eject the tablet inside your vagina where it will dissolve slowly over several hours.

Step 8: After depressing the plunger, gently remove the applicator and dispose of it the same way you would a plastic tampon applicator. The applicator is of no further use and should be discarded properly. Insertion may be done at any time of the day. It is advisable to use the same time daily for all applications of Vagifem® (estradiol vaginal tablets). If you have any questions, please consult your healthcare provider or pharmacist.

Dosage

Vagifem® therapy consists of the following dosing regimen:

One (1) Vagifem® tablet inserted vaginally once daily for the first two (2) weeks, then one (1) tablet inserted twice weekly (for example Tuesday and Friday) for as long as you use Vagifem®.

What are the possible side effects of Vagifem®?

Vagifem® is only used in the vagina; however, the risks associated with oral estrogens should be taken into account.

Side effects are grouped by how serious they are and how often they happen when you are treated.

Serious but less common side effects include:

- Heart attack
- Stroke
- Blood clots
- Dementia
- Breast cancer
- Cancer of the lining of the uterus (womb)
- Cancer of the ovary
- High blood pressure
- High blood sugar
- Gallbladder disease
- Liver problems
- Enlargement of benign tumors of the uterus ("fibroids")

Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:

- New breast lumps
- Unusual vaginal bleeding
- Changes in vision or speech
- Sudden new severe headaches

- Severe pains in your chest or legs with or without shortness of breath, weakness and fatigue

Less serious, but common, side effects include:

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach or abdominal cramps, bloating
- Nausea and vomiting
- Hair loss
- Fluid retention
- Vaginal yeast infection

These are not all the possible side effects of Vagifem®. For more information, ask your healthcare provider or pharmacist for advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What can I do to lower my chances of a serious side effect with Vagifem®?

- Talk with your healthcare provider regularly about whether you should continue using Vagifem®
- If you have a uterus, talk with your healthcare provider about whether the addition of a progestin is right for you

The addition of a progestin is generally recommended for a woman with a uterus to reduce the chance of getting cancer of the uterus. See your healthcare provider right away if you get vaginal bleeding while using Vagifem®.

- Have a pelvic exam, breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you something else

If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often.

- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease

Ask your healthcare provider for ways to lower your chances for getting heart disease.

General information about the safe and effective use of Vagifem®.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Vagifem® for conditions for which it was not prescribed. Do not give Vagifem® to other people, even if they have the same symptoms you have. It may harm them.

Keep Vagifem® out of the reach of children.

This leaflet provides a summary of the most important information about Vagifem®. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Vagifem® that is written for health professionals. You can get

more information by calling the toll free number 1-888-824-4336.

What are the ingredients in Vagifem®?

Vagifem® (estradiol vaginal tablets) are small, white, film-coated tablets containing estradiol. Each tablet also contains hypromellose, lactose monohydrate, maize starch and magnesium stearate. The film coating contains hypromellose and polyethylene glycol.

Each Vagifem® tablet is contained in a disposable applicator, packaged in a blister pack. Cartons contain 8 or 18 applicators with inset tablets.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Do not refrigerate.

[see USP Controlled Room Temperature].

Vagifem® is a registered trademark owned by Novo Nordisk FemCare AG.

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