

PATIENT INFORMATION
IMVEXXY® (im vex' ee)
(estradiol vaginal inserts)

Read this Patient Information before you start using IMVEXXY and each time you get a refill. 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 IMVEXXY (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 IMVEXXY. 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 and older.
- Do not use estrogens with progestogens to prevent heart disease, heart attacks, strokes or dementia.
- Using estrogens with progestogens may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.
- Using estrogens with progestogens may increase your chance of getting dementia, based on a study of women 65 years of age and older.
- Only one estrogen-alone product and dose have been shown to increase your chances of getting strokes, blood clots, and dementia. Only one estrogen with progestogen product and dose have been shown to increase your chances of getting heart attacks, strokes, breast cancer, blood clots, and dementia. Because other products and doses have not been studied in the same way, it is not known how the use of IMVEXXY will affect your chances of having these conditions.
- You and your healthcare provider should talk regularly about whether you still need treatment with IMVEXXY.

What is IMVEXXY?

IMVEXXY is a prescription medicine that contains an estrogen hormone in a vaginal insert.

What is IMVEXXY used for?

IMVEXXY is used after menopause to treat moderate to severe painful intercourse, a symptom of changes in and around your vagina, due to menopause.

Who should not use IMVEXXY?

Do not start using IMVEXXY if you:

- **have 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.

- **have been diagnosed with a bleeding disorder.**

- **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 (womb). If you have or have had cancer, talk with your healthcare provider about whether you should use IMVEXXY.

- **currently have or have had blood clots.**

- **had a stroke or heart attack.**

- **currently have or have had liver problems.**

- **are allergic to IMVEXXY or any of its ingredients.** See the list of ingredients in IMVEXXY at the end of this leaflet.

Before you use IMVEXXY, tell your healthcare provider about all of your medical conditions, including 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 or spotting to find out the cause.
- **have any other medical conditions that may become worse while you are using IMVEXXY.** Your healthcare provider may need to check you more carefully if you have certain medical conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, angioedema (swelling of face and tongue), problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- **are going to have surgery or will be on bed rest.** You may need to stop using IMVEXXY.
- **are pregnant or think you may be pregnant.** Imvexxy is not for pregnant women.
- **are breast feeding.** The hormone in IMVEXXY can pass into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how IMVEXXY works.

IMVEXXY may also affect how other medicines work. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get new medicine.

How should I use IMVEXXY?

For detailed instructions, see the step-by-step instructions for using IMVEXXY at the end of this Patient Information.

- Use IMVEXXY exactly as your healthcare provider tells you to use it.
- IMVEXXY is a vaginal insert that you place in your vagina.
- IMVEXXY is only for use in the vagina. **Do not** take IMVEXXY by mouth (orally).
- Estrogens should be used at the lowest dose possible for your treatment and for only as long as needed.
- Put 1 IMVEXXY insert inside your vagina, 1 time a day at about the same time for the first two weeks.
- Then put 1 IMVEXXY insert into your vagina two times a week, every three to four days (for example, Monday and Thursday), for as long as you use IMVEXXY.

- 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 IMVEXXY.

What are the possible side effects of IMVEXXY?

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

Serious, but less common side effects could include:

- heart attack
- breast cancer
- dementia
- gallbladder disease
- high levels of fat (triglyceride) in your blood
- enlargement of benign tumors of the uterus (“fibroids”)
- stroke
- cancer of the lining of the uterus (womb)
- high or low blood calcium
- visual abnormalities
- liver problems
- worsening of swelling of face and tongue (angioedema) in women with a history of angioedema
- blood clots
- cancer of the ovary
- high blood pressure
- changes in your thyroid hormone levels

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

Common side effects of IMVEXXY include:

- headache
- breast tenderness or pain
- nausea and vomiting

These are not all of the possible side effects of IMVEXXY. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to TherapeuticsMD[®] at 1-888-228-0150.

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

- Talk with your healthcare provider regularly about whether you should continue using IMVEXXY.
- If you have a uterus (womb), talk with your healthcare provider about whether the addition of a progestogen is right for you. In general, the addition of a progestogen is 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

IMVEXXY.

- 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 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 a higher chance of getting heart disease. Ask your healthcare provider for ways to lower your chances of getting heart disease.

General information about the safe and effective use of IMVEXXY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use IMVEXXY for a condition for which it was not prescribed. Do not give IMVEXXY to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about IMVEXXY that is written for health professionals.

What are the ingredients in IMVEXXY?

Active ingredient: IMVEXXY (estradiol vaginal inserts) are small, light pink, tear-shaped inserts that contain estradiol.

Inactive ingredients: Each insert also contains ammonium hydroxide, ethanol, ethyl acetate, ethylene glycol palmitostearate, FD&C Red #40, gelatin, glycerin, isopropyl alcohol, lecithin, medium chain triglycerides, polyethylene glycol, polyethylene glycol stearates, polyvinyl acetate phthalate, propylene glycol, purified water, sorbitol-sorbitan solution, and titanium dioxide. IMVEXXY is supplied in blister cartons of 18 or 8 vaginal inserts.

Instructions for Use

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(estradiol vaginal inserts)

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How should I use IMVEXXY?

- IMVEXXY is an insert only for use in the vagina. Do not take by mouth.
- Put 1 IMVEXXY insert inside your vagina, 1 time a day at about the same time for the first two weeks, then put 1 IMVEXXY insert into your vagina two times a week, every three to four days (for example, Monday and Thursday), for as long as you use IMVEXXY.
- Write down the days you will put in your IMVEXXY insert.
- Wash and dry your hands before handling the IMVEXXY insert.

Step 1: Push 1 IMVEXXY insert through the foil of the blister package.

Figure A



Step 2: Hold the IMVEXXY insert with the larger end between your fingers.

Figure B



Step 3: Select the best position for vaginal insertion that is most comfortable for you to put in the IMVEXXY insert. See Figure C for suggested insertion in the lying down position or Figure D for suggested insertion in the standing position. With the smaller end up, put the insert about two inches into your vagina using your finger.

Figure C

or

Figure D



If you have any questions, please ask your healthcare provider or pharmacist.

How should I store IMVEXXY?

- Store IMVEXXY at room temperature between 68°F to 77°F (20°C to 25°C).
- IMVEXXY packaging is not child-resistant.

Keep IMVEXXY and all medicines out of the reach of children.

For information, go to TherapeuticsMD.com or call TherapeuticsMD, Inc. at 1-877-833-0176

Manufactured for: TherapeuticsMD, Inc., Boca Raton, FL 33431

For patent information, go to TherapeuticsMD.com/patents
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The Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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Principal Display Panel - Imvexxy 4 mcg 8 Count Carton Label

NDC 50261-104-08

Rx only

Imvexxy[®]

4 mcg (estradiol vaginal inserts)

TherapeuticsMD[®]

8 vaginal inserts

FOR VAGINAL USE ONLY