

**PATIENT INFORMATION**  
**Fyavolv™ (FYE-uh-volv)**  
**(norethindrone acetate and ethinyl estradiol tablets USP)**  
**0.5 mg/0.0025 mg and 1 mg/0.005 mg**

Read this Patient Information before you start taking Fyavolv 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 Fyavolv (a combination of estrogen and progestin)?**

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

**What is Fyavolv?**

Fyavolv is a prescription medicine that contains two kinds of hormones, an estrogen and a progestin.

**What is Fyavolv used for?**

Fyavolv is used after menopause to:

• **Reduce moderate to severe hot flashes**

Estrogens are hormones made by a woman's ovaries. The ovaries normally stop making estrogens when a woman is between 45 and 55 years old. This drop in body estrogen levels causes the "change of life" or menopause, the end of monthly menstrual periods. Sometimes both ovaries are removed during an operation before natural menopause takes place. The sudden drop in estrogen levels causes "surgical menopause".

When estrogen levels begin dropping, some women get very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden intense episodes of heat and sweating ("hot flashes" or "hot flushes"). In some women the symptoms are mild, and they will not need to take estrogens. In other women, symptoms can be more severe.

• **Help reduce your chances of getting osteoporosis (thin weak bones)**

If you use Fyavolv only to prevent osteoporosis from menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you. You and your healthcare provider should talk regularly about whether you still need treatment with Fyavolv.

### **Who should not take Fyavolv?**

#### **Do not take Fyavolv if you have had your uterus (womb) removed (hysterectomy).**

Fyavolv contains a progestin to decrease the chance of getting cancer of the uterus. If you do not have a uterus, you do not need a progestin and you should not take Fyavolv.

#### **Do not take Fyavolv 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.
- **currently have or have had certain cancers.**  
Estrogens may increase the chance 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 take Fyavolv.
- **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 Fyavolv or any of its ingredients.**  
See the list of ingredients in Fyavolv at the end of this leaflet.
- **think you may be pregnant**  
Fyavolv is not for pregnant women. If you think you may be pregnant, you should have a pregnancy test and know the results. Do not take Fyavolv if the test is positive and talk to your healthcare provider.

### **What should I tell my healthcare provider before I take Fyavolv?**

#### **Before you take Fyavolv, 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.
- **have any other medical conditions**  
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, angioedema (swelling of face and tongue), or 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**  
Your healthcare provider will let you know if you need to stop taking Fyavolv.
- **are breastfeeding**  
The hormones in Fyavolv can pass into your breast milk.

#### **Tell your healthcare provider about all the medicines you take,**

including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Fyavolv works. Fyavolv may also affect how your other medicines

work. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

**How should I take Fyavolv?**

- Take Fyavolv exactly as your healthcare provider tells you to take it.
- Take 1 Fyavolv tablet at the same time each day.
- You and your healthcare provider should talk regularly (every 3 to 6 months) about the dose you are taking and whether or not you still need treatment with Fyavolv.

**What are the possible side effects of Fyavolv?**

**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
- changes in your thyroid hormone levels
- 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
- hair loss
- fluid retention
- vaginal yeast infection

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

You may report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or FDA at 1-800-FDA-1088.

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

- Talk with your healthcare provider regularly about whether you should continue taking Fyavolv.
- 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 (womb).
- See your healthcare provider right away if you develop vaginal bleeding while taking Fyavolv.
- 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 (breast x-ray), 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 use tobacco, you may have a higher chance for getting heart disease.

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

**How should I store Fyavolv?**

- Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature].

**Keep Fyavolv out of the reach of children.**

**General information about the safe and effective use of Fyavolv.**

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

This leaflet summarizes the most important information about Fyavolv. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about Fyavolv that is written for health professionals.

For more information go to [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com) or call 1-800-399-2561.

**What are the ingredients in Fyavolv?**

**Active Ingredients:** norethindrone acetate and ethinyl estradiol

**Inactive Ingredients:** calcium stearate, corn starch, hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide, vitamin E. Each tablet of 1 mg/0.005 mg also contains FD&C Blue No. 2 Aluminum Lake.

This Patient Information has been approved by the U.S Food and Drug Administration.

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Distributed by:

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Baltimore, Maryland 21202

United States

Manufactured by:

**Lupin Limited**

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India

September 2015

ID#: 238475