

Patient Information Estradiol/Norethindrone Acetate Tablets

Read this Patient Information before you start taking Estradiol/Norethindrone Acetate Tablets 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 Estradiol/Norethindrone Acetate Tablets (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).
- Taking estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.
- Taking 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.
- Taking estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Taking estrogen-alone may increase your chances of getting strokes or blood clots.
- Taking 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 Estradiol/Norethindrone Acetate Tablets.

What are Estradiol/Norethindrone Acetate Tablets?

Estradiol/Norethindrone Acetate Tablets are a prescription medicine that contains two kinds of hormones, an estrogen and a progestin.

What are Estradiol/Norethindrone Acetate Tablets used for?

Estradiol/Norethindrone Acetate Tablets are 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 yrs 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 the 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. You and your healthcare provider should talk regularly about whether or not you still need treatment with Estradiol/Norethindrone Acetate Tablets.

• treat moderate to severe menopausal changes in and around the vagina

You and your healthcare provider should talk regularly about whether you still need treatment with Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg to treat these problems. If you use Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg only to treat your menopausal changes in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.

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

If you use Estradiol/Norethindrone Acetate Tablets 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 Estradiol/Norethindrone Acetate Tablets.

Who should not take Estradiol/Norethindrone Acetate Tablets?

Do not take Estradiol/Norethindrone Acetate Tablets if you have had your uterus (womb) removed (hysterectomy).

Estradiol/Norethindrone Acetate Tablets 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 Estradiol/Norethindrone Acetate Tablets.

Do not take Estradiol/Norethindrone Acetate Tablets 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 Estradiol/Norethindrone Acetate Tablets.

• 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 Estradiol/Norethindrone Acetate Tablets or any of its ingredients

See the list of ingredients in Estradiol/Norethindrone Acetate Tablets at the end of this leaflet.

• think you may be pregnant

Estradiol/Norethindrone Acetate Tablets are not for pregnant women. If you think you may be pregnant, you should have a pregnancy test and know the results. Do not take Estradiol/Norethindrone Acetate Tablets if the test is positive and talk to your healthcare provider.

What should I tell my healthcare provider before taking Estradiol/Norethindrone Acetate Tablets?

Before you take Estradiol/Norethindrone Acetate Tablets, 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 Estradiol/Norethindrone Acetate Tablets.
- **are breast feeding**
The hormones in Estradiol/Norethindrone Acetate Tablets can pass into your breast milk.

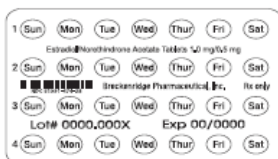
Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how Estradiol/Norethindrone Acetate Tablets work. Estradiol/Norethindrone Acetate Tablets may also affect how your other medicines work. Keep a list of your medicines and show them to your healthcare provider and pharmacist when you get a new medicine.

How should I take Estradiol/Norethindrone Acetate Tablets?

- Take Estradiol/Norethindrone Acetate Tablets exactly as your healthcare provider tells you to take them.
- Take 1 Estradiol/Norethindrone Acetate 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 you still need treatment with Estradiol/Norethindrone Acetate Tablets.

Follow the instructions below to use your Estradiol/Norethindrone Acetate Tablets Dispenser.

Example Dispenser:



How to use the Estradiol/Norethindrone Acetate Tablet Dispenser

1, Beginning regimen
Start the regimen in Row 1 correlating the day of the week to Day 1

2, Daily
Moving across each row of the blister card, continue taking tablets daily correlating to the day of the week

3, End of regimen
If, at the end of Row 4, tablets remain in Row 1, return to take remaining tablets correlating to the day of the week.

Note: All tablets should be taken at the end of the 28-day cycle.

What are the possible side effects of Estradiol/Norethindrone Acetate Tablets?

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 ("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 Estradiol/Norethindrone Acetate Tablets. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or does not go away. You may report side effects to Breckenridge Pharmaceutical, Inc. at 1-800-367-3395 or to FDA at 1-800-FDA-1088.

What can I do to lower my chances of a serious side effect with Estradiol/Norethindrone Acetate Tablets?

- Talk with your healthcare provider regularly about whether you should continue taking Estradiol/Norethindrone Acetate Tablets.
- 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 get vaginal bleeding while taking Estradiol/Norethindrone Acetate Tablets.
- 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 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.

How should I store Estradiol/Norethindrone Acetate Tablets?

- Store Estradiol/Norethindrone Acetate Tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Estradiol/Norethindrone Acetate Tablets in a dry place protected from light.

KEEP Estradiol/Norethindrone Acetate Tablets and all medicines out of the reach of children.

General information about the safe and effective use of Estradiol/Norethindrone Acetate Tablets.

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

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

For more information go to www.bpirx.com or call 1-800-367-3395.

What are the ingredients in Estradiol/Norethindrone Acetate Tablets?

Active ingredients: estradiol and norethindrone acetate

Inactive Ingredients: lactose monohydrate, starch (corn), copovidone, talc, magnesium stearate, hypromellose, and triacetin.

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

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