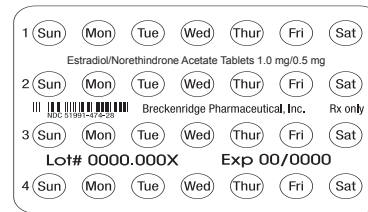


## Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg and 0.5 mg/0.1 mg

### 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.

### Patient Information (January 2010)

#### Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg and 0.5 mg/0.1 mg

Read this Patient Information leaflet before you start taking Estradiol/Norethindrone Acetate tablets and read what you get each time you refill Estradiol/Norethindrone Acetate Tablets. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

#### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT

##### Estradiol/Norethindrone Acetate Tablets (a combination of estrogen and progestin hormones)?

- Estrogens increase the chance of getting cancer of the uterus.

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

- Do not use estrogens with or without progestins to prevent heart disease, heart attacks, or strokes.

Using estrogens with or without progestins may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots.

- Do not use estrogens with or without progestins to prevent dementia.

Using estrogens with or without progestins may increase your risk of dementia.

You and your health care 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 medicine that contains estrogen and progestin hormones.

#### 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 to 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 develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden strong feelings of heat and sweating ("hot flashes" or "hot flushes"). In some women, the symptoms are mild, and they will not need estrogens. In other women, symptoms can be more severe. You and your health care provider should talk regularly about whether you still need treatment with Estradiol/Norethindrone Acetate Tablets.

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

Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use Estradiol/Norethindrone Acetate Tablets only to prevent osteoporosis from menopause, talk with your health care provider about whether a different treatment or medicine without estrogens might be better for you. You and your health care provider should talk regularly about whether you should continue with Estradiol/Norethindrone Acetate Tablets.

Weight-bearing exercises, like walking or running, and taking calcium and vitamin D supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your health care provider before starting them.

Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg is also used after menopause to:

- Treat moderate to severe dryness, itching, and burning in or around the vagina

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

#### Who should not take Estradiol/Norethindrone Acetate Tablets?

##### Do Not Take Estradiol/Norethindrone Acetate Tablets If You Have Had Your Uterus Removed (hysterectomy)

Estradiol/Norethindrone Acetate Tablets contain a progestin to decrease the chances 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 start taking Estradiol/Norethindrone Acetate Tablets if you:

- Have unusual vaginal bleeding
- 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 health care provider about whether you should take Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg.

- Had a stroke or heart attack in the past year
- Currently have or have had blood clots
- Currently have or have had liver problems
- Are allergic to Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg or any of their ingredients

See section entitled, "What are the ingredients in Estradiol/Norethindrone Acetate Tablets?" for a list of ingredients in Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg

- Think you may be pregnant

### Patient Information (January 2010)

#### Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg and 0.5 mg/0.1 mg

#### Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg and 0.5 mg/0.1 mg

### Patient Information (January 2010)

Tell your healthcare provider:

- **If you are breastfeeding**

The hormones in Estradiol/Norethindrone Acetate Tablets can pass into your milk.

- **About all of your medical problems**

Your health care provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing); epilepsy (seizures); migraine; endometriosis; lupus; problems with your heart, liver, thyroid, or 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 Estradiol/Norethindrone Acetate Tablets work. Estradiol/Norethindrone Acetate Tablets 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 taking estrogens.

**How should I take Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg?**

1. Take one Estradiol/Norethindrone Acetate Tablet 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablet 0.5 mg/0.1 mg once a day.
2. Estrogens should be used at the lowest dose possible for your treatment only as long as needed. You and your health care provider should talk regularly (e.g., every 3 to 6 months) about the dose you are taking and whether you still need treatment with Estradiol/Norethindrone Acetate Tablets.

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

**Less common but serious side effects include:**

- **Breast cancer**
- **Cancer of the uterus**
- **Stroke**
- **Heart attack**
- **Blood clots**
- **Dementia**
- **Gallbladder disease**
- **Ovarian cancer**

**Some of the warning signs of serious side effects include:**

- **Breast lumps**
- **Unusual vaginal bleeding**
- **Dizziness and faintness**
- **Changes in speech**
- **Severe headaches**
- **Chest pain**
- **Shortness of breath**
- **Pains in your legs**
- **Changes in vision**
- **Vomiting**

Call your health care provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

**Common side effects include:**

- **Headache**
- **Breast pain**
- **Irregular vaginal bleeding or spotting**
- **Stomach/abdominal cramps, bloating**
- **Nausea and vomiting**
- **Mental depression**
- **Back pain**
- **Weight increase**
- **Hair loss**

**Other side effects include:**

- **High blood pressure**
- **Liver problems**
- **High blood sugar**
- **Fluid retention**
- **Enlargement of benign tumors of the uterus (“fibroids”)**
- **Vaginal yeast infection**
- **Hirsutism**
- **Acne**
- **Weight decrease**
- **Sleep disturbances**
- **Allergic reactions**
- **Nervousness**
- **Mental depression**

These are not all the possible side effects of Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg. For more information, ask your health care provider or pharmacist.

**What can I do to lower my chances of a serious side effect with Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg or Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg?**

- Talk with your health care provider regularly about whether you should continue taking Estradiol/Norethindrone Acetate Tablets.
- See your health care provider right away if you get vaginal bleeding while taking Estradiol/Norethindrone Acetate Tablets.
- Have a breast exam and mammogram (breast X-ray) every year unless your health care provider tells you otherwise. 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 health care provider for ways to lower your chances for getting heart disease.

**Have an annual gynecologic exam**

**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.

**Keep Estradiol/Norethindrone Acetate Tablets out of the reach of children**

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

**What are the ingredients in Estradiol/Norethindrone Acetate Tablets 1.0 mg/0.5 mg?**

Each tablet contains 1.0 mg estradiol and 0.5 mg norethindrone acetate. Each 1.0/0.5 mg tablet also contains lactose monohydrate, starch (corn), copovidone, talc, magnesium stearate, hypromellose, and triacetin for oral administration.

**What are the ingredients in Estradiol/Norethindrone Acetate Tablets 0.5 mg/0.1 mg?**

Each tablet contains 0.5 mg estradiol and 0.1 mg norethindrone acetate. Each 0.5 mg/0.1 mg tablet also contains lactose monohydrate, starch (corn), copovidone, talc, magnesium stearate, hypromellose, and triacetin for oral administration.

Estradiol/Norethindrone Acetate Tablets 1.0 mg/ 0.5 mg and 0.5 mg/0.1 mg are supplied in a calendar blister pack containing 28 tablets.

Store at 20 - 25 °C (68 - 77 °F) [see USP Controlled Room Temperature]

**Rx only**

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