Estradiol vaginal tablets

MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?

ESTRADIOL (es tra DYE ole) vaginal tablet is used to help relieve symptoms of vaginal irritation and dryness that occurs in some women during menopause.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

This medicine is only for use in the vagina. Do not take by mouth. Wash your hands before and after use. Read package directions carefully. Unwrap the pre-filled applicator package. Lie on your back, part and bend your knees. Gently insert the applicator tip high in the vagina and push the plunger to release the tablet into the vagina. Gently remove the applicator. Throw away the applicator after use. Do not use your medicine more often than directed. Finish the full course prescribed by your doctor or health care professional even if you think your condition is better. Do not stop using except on the advice of your doctor or health care professional.

Talk to your pediatrician regarding the use of this medicine in children.

A patient package insert for the product will be given with each prescription and refill. Read this sheet carefully each time. The sheet may change frequently.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- Abnormal vaginal bleeding
- Blood vessel disease or blood clots
- Breast, cervical, endometrial, ovarian, liver, or uterine cancer
- Dementia
- Diabetes
- Gallbladder disease
- Heart disease or recent heart attack
- High blood pressure
- High cholesterol
- High level of calcium in the blood
- Hysterectomy
- Kidney disease
- Liver disease
- Migraine headaches
- Protein C deficiency
- Protein S deficiency
- Stroke
- Systemic lupus erythematosus (SLE)
- Tobacco smoker
- An unusual or allergic reaction to estrogens, other hormones, medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

Do not take this medicine with any of the following medications:

- Aromatase inhibitors like aminoglutethimide, anastrozole, exemestane, letrozole, testolactone

This medicine may also interact with the following medications:

- Antibiotics used to treat tuberculosis like rifabutin, rifampin and rifapentene
- Raloxifene or tamoxifen
- Warfarin
This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Breast tissue changes or discharge
- Changes in vision
- Chest pain
- Confusion, trouble speaking or understanding
- Dark urine
- General ill feeling or flu-like symptoms
- Hair loss
- Increased hunger or thirst
- Increased urination
- Symptoms of vaginal infection like itching, irritation or unusual discharge
- Unusually weak or tired

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- Light-colored stools
- Nausea, vomiting
- Pain, swelling, warmth in the leg
- Right upper belly pain
- Severe headaches
- Shortness of breath
- Sudden numbness or weakness of the face, arm or leg
- Trouble walking, dizziness, loss of balance or coordination
- Unusual vaginal bleeding
- Yellowing of the eyes or skin

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Where should I keep my medicine?

Keep out of the reach of children.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Throw away any unused medicine after the expiration date.

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What should I watch for while using this medicine?

Visit your health care professional for regular checks on your progress. You will need a regular breast and pelvic exam. You should also discuss the need for regular mammograms with your health care professional, and follow his or her guidelines.

This medicine can make your body retain fluid, making your fingers, hands, or ankles swell. Your blood pressure can go up. Contact your doctor or health care professional if you feel you are retaining fluid.

If you have any reason to think you are pregnant; stop taking this medicine at once and contact your doctor or health care professional.

Tobacco smoking increases the risk of getting a blood clot or having a stroke, especially if you are more than 35 years old. You are strongly advised not to smoke.

If you wear contact lenses and notice visual changes, or if the lenses begin to feel uncomfortable, consult your eye care specialist.

If you are going to have elective surgery, you may need to stop taking this medicine beforehand. Consult your health care professional for advice prior to scheduling the surgery.