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Drug NDC: 65162-0226-21
Drug Name: YUVAFEM

What is this medicine?

ESTRADIOL (es tra DYE ole) vaginal insert is used to treat females who experience painful sexual intercourse, a symptom of menopause that occurs due to changes in and around the vagina.

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 for vaginal use only. Do not take by mouth. Follow the directions on the prescription label. Read package directions carefully before using. Wash hands before and after use. Use this medicine at bedtime. Do not use it more often than directed. Do not stop using except on your doctor's advice. Talk to your pediatrician regarding the use of this medicine in children. This medicine is not approved for use in children.

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.

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.

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 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 if I miss a dose?

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

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

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 lumps, tissue changes, or discharge; increased blood pressure; signs and symptoms of liver injury like dark yellow or brown urine; general ill feeling or flu-like symptoms; light-colored stools; loss of appetite; nausea; right upper belly pain; unusually weak or tired; yellowing of the eyes or skin; signs and symptoms of a blood clot such as breathing problems; changes in vision or speech; chest pain; severe, sudden headache; pain, swelling, warmth in the leg; trouble speaking; sudden numbness or weakness of the face, arm or leg; swelling in your ankles, legs, or feet; vaginal discharge, itching, or odor; unusual vaginal bleeding. Side effects that usually do not require medical attention (report these to your doctor or health care professional if they continue or are bothersome): breast tenderness or pain; headache; nausea

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.

What may interact with this medicine?

Do not take this medicine with any of the following medications: aromatase inhibitors like aminoglutethimide, anastrozole, exemestane, letrozole, toremifene; This medicine may also interact with the following medications: antibiotics used to treat tuberculosis like rifabutin, rifampin and rifapentine; 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.