

Estradiol Valerate Injection, USP: Puncturing the vial

Estradiol Valerate Injection, USP



For Patient Use

What is Estradiol Valerate Injection used for?

Estradiol Valerate Injection 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 to 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 the estrogen levels begin dropping, some women develop very uncomfortable symptoms, such as feeling 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 healthcare provider should talk regularly about whether you still need treatment with Estradiol Valerate Injection.

- **treat moderate to severe dryness, itching, and burning in and around the vagina.** You and your healthcare provider should talk regularly about whether you still need treatment with Estradiol Valerate Injection to control these problems. If you use Estradiol Valerate Injection only to treat your dryness, itching, and burning in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.

This instruction will provide information on how to correctly and safely puncture the vial using a syringe to remove the medication from an Estradiol Valerate vial.

- Wash your hands before handling the vial or preparing the medication
- Read the patient labeling instructions that accompany your product
- Store the vial at room temperature between 20° to 25°C (68° to 77°F)
- Estradiol Valerate Injection, USP is a multiple-dose vial
 - Verify that the expiration date on the label has not passed
 - Verify that you have all necessary supplies for injection, including sharps container, 1cc syringe, 20g needle, alcohol prep pad, and medication vial
- Note the date of first use on the vial with a pen or marker. This vial should not be used beyond 28 days from time of first vial puncture
 - Each time you use the vial, inspect the vial for particles. If you see anything floating, or if the solution is not clear, discard the vial and use a new vial
- Use a washed and clean surface, that is not near any potential sources of contamination, including sinks or other water sources
- Prior to withdrawal, confirm the prescribed dose (mg) and volume of solution (mL) to be administered per provider instructions

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Estradiol Valerate Injection, USP: Puncturing the vial (cont'd)

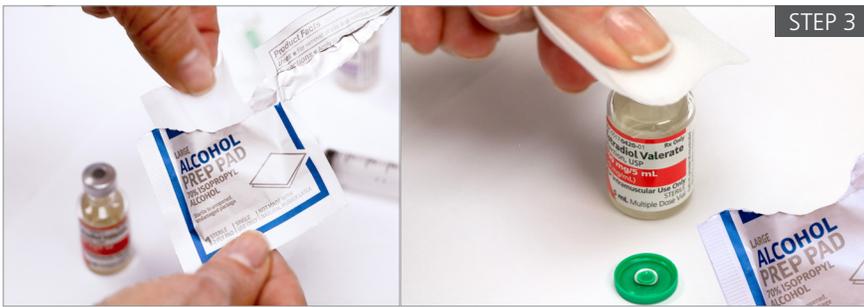


Supplies you need for your injection: A sharps container, 1cc syringe, 20g needle, alcohol prep pad, and medication vial



Upon first use: Remove the plastic cap

For all uses:



Open the alcohol wipe and cleanse the rubber stopper in a circular motion multiple times



Remove the syringe from the packaging and remove the syringe cap



Open the needle wrapper holding by the capped end. Place the needle onto the syringe opening and twist to lock into place. **Never handle the needle directly**



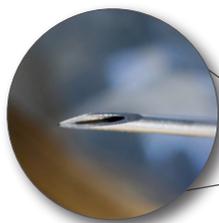
Remove the cap from the needle



Pull back plunger to the prescribed volume and fill syringe with air

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Estradiol Valerate Injection, USP: Puncturing the vial (cont'd)



Insert the needle into the rubber stopper at a 45–60° angle with the opening of the needle tip facing up (ie, away from the stopper), sometimes referred to as “bevel up” towards the center of the stopper



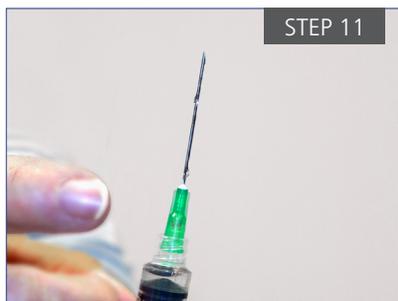
Bring the syringe up to a 90° angle (vertical)



Push in the plunger so the air is released from the syringe into the vial



Keeping the needle in the stopper, invert the vial and syringe. Pull back the plunger until the medicine fills to the prescribed volume



Remove the syringe from the vial

Prepare for injection per your provider's instructions.

Following administration of the product per the instructions in the labeling, and your provider's instruction, put needle and syringe in a sharps container, discard alcohol wipe and plastic vial cap. Do not reuse syringes or needles.

For repeated use:

Select a new puncture site, with a new needle and syringe, each time you use the vial. Do not use the same puncture site.

Do not share your needles or syringes.

Do not share the vial of Estradiol Valerate even if a different needle is used.

Do not use unless you have received proper training from your healthcare provider.

Important Safety Information

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ESTRADIOL VALERATE INJECTION (AN ESTROGEN HORMONE)?

- Estrogens increase the chances 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 healthcare 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 chances of getting heart attacks, strokes, breast cancer, and blood clots. Using estrogens with progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with Estradiol Valerate Injection.

What is Estradiol Valerate Injection?

Estradiol Valerate Injection is a medicine that contains estrogen hormones.

Who should not take Estradiol Valerate Injection?

Do not take estradiol valerate if you:

- Have unusual vaginal bleeding
- Currently have or have had certain cancers. Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or had cancer, talk to your healthcare provider about whether you should take Estradiol Valerate Injection.
- 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 Valerate Injection or any of its ingredients.
- Think you may be pregnant

Tell your healthcare provider:

- If you are breastfeeding. The hormone in Estradiol Valerate Injection can pass into your milk.
- About all of your medical problems. Your healthcare 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, 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 Valerate Injection works. Estradiol Valerate Injection 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.

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

These are some of the warning signs of serious side effects:

- 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 healthcare 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
- 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

These are not all the possible side effects of Estradiol Valerate Injection. For more information, ask your healthcare provider or pharmacist.

For additional safety information, including BOXED WARNING, please see [Full Prescribing Information](#) including the Patient Information on the last page.

You are encouraged to report adverse drug events to American Regent, Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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