



Estradiol Valerate

Injection, USP

FREQUENTLY ASKED QUESTIONS

1. Is Estradiol Valerate Injection, USP a boxed warning product?

Yes

ESTROGENS INCREASE THE RISK OF ENDOMETRIAL CANCER

Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding. There is no evidence that the use of “natural” estrogens results in a different endometrial risk profile than synthetic estrogens at equivalent estrogen doses.

Estrogens and progestins should not be used for the prevention of cardiovascular disease. The Women’s Health Initiative (WHI) study reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) relative to placebo.

The Women’s Health Initiative Memory Study (WHIMS), a substudy of WHI, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with oral conjugated estrogens plus medroxyprogesterone acetate relative to placebo. It is unknown whether this finding applies to younger postmenopausal women or to women taking estrogen alone therapy.

Other doses of oral conjugated estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens and progestins were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar. Because of these risks, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

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

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 by calling 1-800-FDA-1088.

2. What are the ingredients in Estradiol Valerate Injection, USP?

Estradiol Valerate Injection, USP is supplied in 5 mL multiple-dose vials:

- 20 mg/mL vial contains estradiol valerate in a solution of benzyl benzoate, benzyl alcohol, and castor oil
- 40 mg/mL vial contains estradiol valerate in a solution of benzyl benzoate, benzyl alcohol, and castor oil¹

3. What is the preservative in Estradiol Valerate Injection, USP?

20 mg benzyl alcohol per mL

4. How is estradiol valerate administered?

Estradiol Valerate Injection, USP contains estradiol valerate, a long-acting estrogen in sterile oil solutions for intramuscular use.

5. How stable is the vial after puncture?

The extended stability of Estradiol Valerate Injection, USP after vial puncture has not been studied. Chapter 797 of *United States Pharmacopeia* recommends up to 28 days as the beyond-use date for opened or “entered” (ie, needle-punctured) multi-dose vials of sterile pharmaceutical injection containing antimicrobial preservatives.²

6. How should Estradiol Valerate Injection, USP be stored?

Store Estradiol Valerate Injection, USP at room temperature between 20°C to 25°C (68°F to 77°F). (See USP-Controlled Room Temperature.)¹ PROTECT FROM LIGHT. Store vial in carton until used.

7. Is Estradiol Valerate Injection, USP latex-free?

Yes. The vial closure is not made with natural rubber latex.

Estradiol Valerate

Injection, USP

Pack NDC#	Strength	Supplied as	Shelf pack
0517-0420-01	20 mg/mL	5 mL Multiple-dose vial	1
0517-0440-01	40 mg/mL	5 mL Multiple-dose vial	1

You are encouraged to report adverse drug events (ADEs) to American Regent:

T 1.800.734.9236; E pv@americanregent.com; F 1.610.650.0170

ADEs may also be reported to the FDA:

1.800.FDA.1088 or www.fda.gov/medwatch

Medical information:

T 1.888.354.4855 (9:00 am – 5:00 pm Eastern Time, Monday – Friday)

www.americanregent.com/medical-affairs

For medical information outside of normal business hours that cannot wait until the next business day, please call 1.877.845.6371

REFERENCES:

1. Estradiol Valerate Injection, USP [package insert]. Shirley, NY: American Regent, Inc. 11/2019.
2. The National Formulary. *United States Pharmacopeia*. United States Pharmacopeial Convention; 2008.

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