

## **DEPO<sup>®</sup>-Estradiol**

### **Estradiol cypionate injection, USP**

**DEPO-Estradiol Injection (estradiol cypionate USP) is an estrogen product for injection. The information below is that which the U.S. Food and Drug Administration requires be provided for all patients taking estrogens. For further information ask your doctor.**

### **PATIENT INFORMATION**

## **DEPO-Estradiol<sup>®</sup>**

### **Brand of estradiol cypionate injection, USP**

Read this PATIENT INFORMATION before you start taking DEPO-Estradiol and read what you get each time you refill DEPO-Estradiol. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT DEPO-ESTRADIOL (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 uterine (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. You and your healthcare provider should talk regularly about whether you still need treatment with DEPO-Estradiol.

### **What is DEPO-Estradiol**

DEPO-Estradiol injection is an estrogen product. The information below is that which the U.S. Food and Drug Administration requires be provided for all patients taking estrogens. For further information ask your doctor.

## What is DEPO-Estradiol used for?

DEPO-Estradiol is used during and after menopause to:

- reduce moderate or severe menopausal symptoms. 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 which causes the "change of life" or menopause (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"). Using estrogen drugs can help the body adjust to lower estrogen levels and reduce these symptoms. Most women have only mild menopause symptoms or none at all and do not need estrogen drugs for these symptoms.

- **treat moderate to severe itching, burning, and dryness in or around the vagina.**

You and your healthcare provider should talk regularly about whether you still need treatment with DEPO-Estradiol to control these problems.

## DEPO-Estradiol is also used to:

- treat certain conditions in women before menopause if their ovaries do not make enough estrogen.

## Who should not take DEPO-Estradiol?

Do not start taking DEPO-Estradiol 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 with your healthcare provider about whether you should take DEPO-Estradiol.

- **had a stroke or heart attack in the past year.**
- **currently have or have had blood clots.**
- **are allergic to DEPO-Estradiol or any of its ingredients.**

See the end of this leaflet for a list of ingredients in DEPO-Estradiol.

- **think you may be pregnant.**

**Tell your healthcare provider:**

- **if you are breastfeeding.**

The hormone in DEPO-Estradiol 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, or 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 DEPO-Estradiol works. DEPO-Estradiol 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 DEPO-Estradiol?**

Take DEPO-Estradiol as directed by your healthcare provider.

Estrogens should be used only as long as needed. You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about whether you still need treatment with DEPO-Estradiol.

### **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
- 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

**Other side effects include:**

- High blood pressure
- Liver problems
- High blood sugar
- Fluid retention
- Enlargement of benign tumors of the uterus (“fibroids”)
- Vaginal yeast infections
- Hair loss

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

## What can I do to lower my chances of getting a serious side effect with DEPO-Estradiol?

- Talk with your healthcare provider regularly about whether you should continue taking DEPO-Estradiol. If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you. See your healthcare provider right away if you get vaginal bleeding while taking DEPO-Estradiol. Have a breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you something else. 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 examinations 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 healthcare provider for ways to lower your chances for getting heart disease.

## General information about safe and effective use of DEPO-Estradiol

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take DEPO-Estradiol for conditions for which it was not prescribed. Do not give DEPO-Estradiol to other people, even if they have the same symptoms you have. It may harm them. **Keep DEPO-Estradiol out of the reach of children.**

This leaflet provides a summary of the most important information about DEPO-Estradiol. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about DEPO-Estradiol that is written for health professionals. You can get more information by calling the toll free number 1-888-691-6813.

You are cautioned to discuss very carefully with your doctor or healthcare provider all the possible risks and benefits of long-term estrogen and progestin treatment as they affect you personally.

Rx only



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