

0.9 mg:

The tablets are oval, light blue-green, film-coated, and debossed with “E” on one side and “5” on the reverse and are available in bottles of:

100 Tablets	NDC 51285-409-02
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1.25 mg:

The tablets are oval, yellow, film-coated, and debossed with “E” on one side and “4” on the reverse and are available in bottles of:

100 Tablets	NDC 51285-410-02
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Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Dispense in a tight container with a child-resistant closure.

Pharmacist: Include one “Patient Information” leaflet with each prescription.

Revised April 2007

PATIENT INFORMATION

Revised APRIL 2007

Read this **Patient Information** leaflet before you start taking ENJUVIA, and read what you get each time you refill ENJUVIA. 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 ENJUVIA (AN ESTROGEN HORMONE MIXTURE)?

- Estrogens increase the chance of getting cancer of the uterus. Report any unusual vaginal bleeding right away while you are taking Enjuvia. 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, or dementia. Using estrogens with or without progestins may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots. Using estrogens, with or without progestins, may increase your risk of dementia, based on a study of women age 65 years or older. You and your healthcare provider should talk regularly about whether you still need treatment with Enjuvia.

What is ENJUVIA?

ENJUVIA is a medicine that contains a mixture of estrogen hormones.

What is ENJUVIA used for?

ENJUVIA 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 and 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 feelings 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 ENJUVIA.

- **Treat moderate to severe vaginal dryness and pain with sex, associated with menopause**

You and your healthcare provider should talk regularly about whether you still need treatment with ENJUVIA to control these problems. If you use ENJUVIA only to treat your vaginal dryness, or pain with sex, talk with your healthcare provider about whether a topical vaginal product might be better for you.

Who should not take ENJUVIA?

Do not start taking ENJUVIA 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 have had cancer, talk with your healthcare provider about whether you should take ENJUVIA.

- **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 ENJUVIA or any of its ingredients**

See the end of this leaflet for a list of ingredients in ENJUVIA.

- **Think you may be pregnant**

Tell your healthcare provider:

- **If you are breastfeeding**

The hormones in ENJUVIA 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, 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 ENJUVIA works. ENJUVIA may also affect how your other medicines work.

- **If you are going to have surgery or will be on bedrest**

You may need to stop taking estrogens.

How should I take ENJUVIA?

- Take one ENJUVIA tablet by mouth at the same time each day.
- If you miss a dose, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your normal schedule. Do not take 2 doses at the same time.
- Estrogens should be used at the lowest dose possible for your treatment only as long as needed. You and your healthcare provider should talk regularly (e.g., every 3 to 6 months) about the dose you are taking and whether you still need treatment with ENJUVIA.
- ENJUVIA may be taken with or without food.

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**

Some of the warning signs of serious side effects include:

- **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 symptoms that concern 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 ENJUVIA. For more information, ask your health-care provider or pharmacist.

What can I do to lower my chances of a serious side effect with ENJUVIA?

- Talk with your healthcare provider regularly about whether you should continue taking ENJUVIA.
- If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you.
- **In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.**
- See your healthcare provider right away if you get vaginal bleeding while taking ENJUVIA.
- Have a breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you otherwise. 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 exams 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 a higher chance of getting heart disease. Ask your healthcare provider for ways to lower your chance of getting heart disease.

Have an annual gynecologic exam.

General information about safe and effective use of ENJUVIA.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take ENJUVIA for conditions for which it is not prescribed. Do not give ENJUVIA to other people, even if they have the same symptoms you have. It may harm them.

Keep ENJUVIA out of the reach of children.

This leaflet provides a summary of the most important information about ENJUVIA. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about ENJUVIA that is written for healthcare professionals.

You may also obtain further information by calling the toll free number 1-877-405-0369 or by visiting our website at www.ENJUVIA.com.

What are the ingredients in ENJUVIA?

ENJUVIA tablets for oral administration are available in 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg and 1.25 mg strengths of synthetic conjugated estrogens, B. These tablets contain the following inactive ingredients: ascorbyl palmitate, butylated hydroxyanisole, colloidal silicon dioxide, edetate disodium dehydrate, plasticized ethylcellulose, hypromellose, lactose monohydrate, magnesium stearate, purified water, iron oxide red, titanium dioxide, polyethylene glycol, polysorbate 80, triacetate and triacetin/glycerol. In addition, the 0.45 mg tablets contain iron oxide black and iron oxide yellow; the 0.9 mg tablets also contain D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake and FD& C yellow no. 6 aluminum lake; and the 1.25 mg tablets contain iron oxide yellow.

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