Important Safety Information

Important Information: ENJUVIA is a medicine that contains estrogen hormones. It is prescribed for relief of moderate-to-severe symptoms (hot flashes and night sweats) associated with menopause.

Important health information you should know when taking estrogens like ENJUVIA:

- Estrogens increase the risk for cancer of the uterus (womb). If you experience persistent or recurring vaginal bleeding while taking estrogens let your doctor know right away, as this could be a warning sign for cancer. Your doctor should check for the cause of any unusual vaginal bleeding after menopause.
- Estrogens (alone, or in combination with progestins) should not be used to prevent heart disease, heart attacks, strokes or dementia.
- Estrogens (alone or in combination with progestins) may increase the risk of heart attack, stroke, blood clots, breast cancer and dementia. Because of these risks, estrogens should be used at the lowest dose for the shortest time period of time. You and your doctor should talk regularly to determine whether you still need treatment with ENJUVIA.

Teva Women’s Health, Inc. reserves the right to limit enrollment of patients to the Enjuvia Patient Assistance Program at any time.

The program administrators reserve the right any time and without notice to modify the application form, modify or discontinue any or all of the program and the related eligibility criteria; or at any time terminate assistance provided by the program.

ENJUVIA® is a registered trademark of Teva Women’s Health, Inc.

December 2009
PATIENT INFORMATION (Please Print)

First Name: ___________________________ MI: __________ Last Name: ___________________________

Address: _______________________________ Zip Code: __________ City: ___________________________

State: __________ Phone: __________ Date of Birth: (mm/dd/yyyy) __________

Social Security #: __________ Patient’s Diagnosis (ICD.9 Code): ___________________________

PATIENT’S INCOME:

Current gross annual on income (including patient) Number of children:

household income: $ ___________________________ Number of household members dependent ___________________________

Patient financial documentation must be included with this application. Proof of income includes copies of both: a) your federal tax return (Form 1040 or 1040EZ) for prior tax year, and b) all other recent documents that show income paid to you (or your spouse if married), such as: wage and tax statements (W-2 forms), Social Security, Pension, or Railroad Retirement statements (SSA-1099 or similar), Statements of interest, dividends, or other income (1099-INT, 1099, 1099-DIV, or other forms)

PATIENT’S INSURANCE AND PRESCRIPTION COVERAGE (PARTIAL OR FULL)

Check all that apply:

☐ Medicare ☐ Medicare Advantage (MA) ☐ Includes Rx ☐ Private Foundation ☐ Includes Rx

☐ Medicaid ☐ State/Local Government ☐ Includes Rx ☐ Medicare Medigap ☐ Includes Rx

☐ Medicaid QMB ☐ Federal Program ☐ Includes Rx ☐ Private Prescription Drug Plan (PDP)

☐ Uninsured ☐ Private Insurance / HMO ☐ Includes Rx ☐ Other: Specify:

PATIENT/APPLICANT DECLARATION

I understand that completing this form does not ensure that I will qualify for this program. I verify that the information provided in this qualification form is complete and accurate. I agree to notify the Enjuvia Patient Assistance Program if I obtain prescription drug coverage or if I no longer meet the income criteria. I understand that the program administrators reserve the right any time and without notice to modify the application form, modify or discontinue any or all of the program and the related eligibility criteria; or terminate assistance provided by the program at any time. No claim may be made to any third party payer for payment for product or administration of product provided under the Program.

Patient’s Original Signature: ___________________________ Date: (mm/dd/yyyy) ___________________________

PRESCRIBER’S INFORMATION (Please Print)

First Name: ___________________________ MI: __________ Last Name: ___________________________

Facility: _______________________________ Office Contact Name: ___________________________

Street: _______________________________ Bldg/Suite/Floor/Room: ___________________________

City: _______________________________ State: __________ Zip Code: __________ Phone: __________

Fax: _______________________________ Specialty: ___________________________ State License #: __________

E-Mail Address: ___________________________

When you provide your e-mail address, you agree that Teva Women’s Health, Inc. and its agents may contact you about health-related materials or programs.

ENJUVIA DOSAGE (This section of the form will serve as the Enjuvia prescription) Quantity: 1 bottle of 100 tablets

Check dosage: ☐ Enjuvia® 0.3 mg tablets ☐ Enjuvia® 0.45 mg tablets

☐ Enjuvia® 0.625 mg tablets ☐ Enjuvia® 0.9 mg tablets ☐ Enjuvia® 1.25 mg tablets

☐ QD sig – one tablet daily ☐ QHS sig – one tablet every bedtime ☐ Other:

PRESCRIBER ATTESTATION

I represent that the information contained in this application is complete and accurate to the best of my knowledge. To the best of my knowledge, this patient has no prescription insurance coverage for the requested medication, including Medicaid or other public programs, and the patient has insufficient financial resources to pay for the prescribed therapy. No claim may be made to any third party payer for payment of Enjuvia® provided by this Patient Assistance Program. Enjuvia® received for this patient may not be sold or traded, may not be returned for credit, and is not a sample. I understand that the Enjuvia® Patient Assistance Program has the right to modify or discontinue this program and its eligibility requirements, or to terminate assistance, at any time and without prior notice. Please indicate that you agree to these terms by signing below. Your signature also confirms that there is a valid medical need for this patient’s prescription for Enjuvia®.

Prescriber’s Original Signature: ___________________________ Date: (mm/dd/yyyy) ___________________________
Patient Authorization to Disclose Protected Health Information

To the Patient: During the course of your participation in the Enjuvia® Patient Assistance Program, you or your caregiver and your health care professional will provide personal identifying information to Teva Women’s Health, Inc., its affiliated companies and subcontractors on a need-to-know basis for purposes of administering the Enjuvia® Patient Assistance Program (the “Program”). This information may constitute Protected Health Information (PHI) under the privacy rules of the Health Insurance Portability and Accountability Act (HIPAA), and you need to authorize your health care professional and caregiver, if any, to release your PHI to the Teva Team and authorize the Teva Team to use the PHI for the Program.

Authorization Statement

I, (Patient’s Name) , authorize my prescribing healthcare professional, (HCP’s Name) (HCP’s Address) and caregiver as deemed necessary to disclose any personal identifying information to Teva Women’s Health Inc., its affiliated companies and subcontractors (the “Teva Team”) on a need to know basis to use for purposes of administering the Program for the duration of my participation in the Program. Although the Teva Team values my privacy and intends to take reasonable and appropriate measures to protect the information provided from inappropriate disclosure and to use the information only for administering the Program or as required by law, I understand that once information is disclosed to the Teva Team, it may no longer be protected under federal privacy laws and could be redisclosed to others.

I understand that I may refuse to sign this authorization, and my right to treatment, insurance enrollment, eligibility for insurance benefits or my receipt of Enjuvia® are not conditioned on my signing this authorization. However, if I do not sign this authorization, I will not be able to participate in the Program.

I understand that I may revoke this authorization, in writing, at any time, except to the extent action has been taken in reliance on it, by addressing such revocation to Enjuvia® Patient Assistance Program 250 Phillips Blvd, Ste 250, Ewing, NJ 08618 (your healthcare professional will be advised) and that only a written revocation addressed to the Program will constitute an effective withdrawal of my authorization. I understand that I may request a copy of this form from the Enjuvia® Assistance Program.

Required Signature

Signature of patient or legal representative __________________________ Date __________________________

If signed by patient’s legal representative, complete the following:

Print name of legal representative: ________________________________________

Describe representative’s authority to act for patient: ________________________________________

******************************************************************************************

Important:

To the Patient:

Once you have completed and signed this authorization form, please give it to your prescriber. Do not send it to the Enjuvia® Patient Assistance Program.

To the Healthcare Professional:

Retain a copy of the Patient Authorization to Disclose Protected Health Information for your records. Please return the original copy of this signed form along with the completed Qualification application form to the Enjuvia® Patient Assistance Program, 250 Phillips Blvd, Ste 250, Ewing, NJ 08618 or fax to 1.800.685.2577.

Enjuvia® is a registered trademark of Teva Women’s Health, Inc.

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ENJUVIA BRIEF SUMMARY 8.25 X 11_260983_W  3/7/06  2:58 PM  Page 1

ESTROGENS INCREASE THE RISK OF ENDOMETRIAL CANCER

Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding. The risk of endometrial cancer is increased in a different risk profile from synthetic estrogen at equivalent doses. (See WARNINGS, Malignant neoplasm, Endometrial cancer.)

CARDIOVASCULAR AND OTHER RISKS

Estrogens and progestins may increase the risk of cardiovascular disease and other conditions. (See WARNINGS, Cardiovascular disease and other conditions.)

INDICATIONS AND USAGE: ENJUVIA tablets are indicated for the treatment of moderate to severe vasomotor symptoms associated with the menopause.

CONTRAINDICATIONS: ENJUVIA tablets should not be used in individuals with any of the following conditions:

1. Unadvised analgesic paroxysmal bleeding.
2. Known, suspected, or history of cancer of the breast, ovarian, endometrial, or other hormone-dependent neoplasm.
3. Known, suspected, or history of conditions that might be influenced by this factor, such as a cardiac or renal dysfunction, warrant the use of estrogens.
4. Known or suspected pregnancy.
5. Known significant hypercoagulable state.
6. History of stroke, transient ischemic attack, or myocardial infarction.
7. Moderate to severe hypertension, or conditions that could be worsened by an increase in blood pressure.
8. Known or suspected estrogen-sensitive neoplasms.
9. Known or suspected pregnancy.

WARNINGS: See BOXED WARNINGS. The use of unopposed estrogens in a woman who has a uterus, even if she has had a hysterectomy, should be considered. 10. Exacerbation of preexisting conditions: Estrogens and estrogen/progestin therapy has been associated with an increased risk of cardiovascular disease (CVD) and endometrial cancer.

ADVERSE REACTIONS

Most of the adverse reactions are hormonal in nature and are usually mild and transient. Some adverse reactions may occur at any time. The frequency of adverse reactions is described in an age-related manner.

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