

## **PATIENT INFORMATION**

### **PREMPRO<sup>®</sup>**

(Conjugated Estrogens/Medroxyprogesterone Acetate Tablets)

### **PREMPHASE<sup>®</sup>**

(Conjugated Estrogens plus Medroxyprogesterone Acetate Tablets)

Read this PATIENT INFORMATION before you start taking PREMPRO or PREMPHASE and read what you get each time you refill your PREMPRO or PREMPHASE prescription. 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 PREMPRO and PREMPHASE (combinations of estrogens and a progestin)?**

- Do not use estrogens with progestins to prevent heart disease, heart attacks, strokes, or dementia (decline of brain function)
- Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots
- Using estrogens with progestins may increase your chance of getting dementia, based on a study of women age 65 years or older
- Do not use estrogen-alone to prevent heart disease, heart attacks, or dementia
- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb)
- Using estrogen-alone may increase your chances of getting strokes or blood clots
- Using estrogen-alone may increase your chance of getting 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 PREMPRO or PREMPHASE

#### **What is PREMPRO or PREMPHASE?**

PREMPRO or PREMPHASE are medicines that contain two kinds of hormones, estrogens and a progestin.

#### **PREMPRO or PREMPHASE 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 get 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 to take estrogens. In other women, symptoms can be more severe.

- **Treat menopausal changes in and around the vagina**

You and your healthcare provider should talk regularly about whether you still need treatment with PREMPRO or PREMPHASE to control these problems. If you use PREMPRO or PREMPHASE only to treat your menopausal changes in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.

- **Help reduce your chances of getting osteoporosis (thin weak bones)**

Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use PREMPRO or PREMPHASE only to prevent osteoporosis due to menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you. Weight-bearing exercise, like walking or running, and taking calcium (1500 mg/day of elemental calcium) and vitamin D (400-800 IU/day) supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your healthcare provider before starting them.

You and your healthcare provider should talk regularly about whether you still need treatment with PREMPRO or PREMPHASE.

## **Who should not take PREMPRO or PREMPHASE?**

**Do not take PREMPRO or PREMPHASE if you have had your uterus (womb) removed (hysterectomy).**

PREMPRO and PREMPHASE contain a progestin to decrease the chance of getting cancer of the uterus. If you do not have a uterus, you do not need a progestin and you should not take PREMPRO or PREMPHASE.

**Do not take PREMPRO or PREMPHASE if you:**

- **Have unusual vaginal bleeding**
- **Currently have or have had certain cancers**

Estrogens may increase the chance 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 use PREMPRO or PREMPHASE.

- **Had a stroke or heart attack**
- **Currently have or have had blood clots**
- **Currently have or have had liver problems**
- **Have been diagnosed with a bleeding disorder**
- **Are allergic to PREMPRO or PREMPHASE or any of their ingredients**

See the end of this leaflet for a list of ingredients in PREMPRO and PREMPHASE.

- **Think you may be pregnant**

#### **Tell your healthcare provider**

- **If you have any unusual vaginal bleeding**

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.

- **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), diabetes, 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 PREMPRO or PREMPHASE works. PREMPRO or PREMPHASE 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 and progestins.

- **If you are breastfeeding**

The hormones in PREMPRO and PREMPHASE can pass into your milk.

#### **How should I take PREMPRO or PREMPHASE?**

- Take one PREMPRO or PREMPHASE tablet 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 (for example, every 3 to 6 months) about the dose you are taking and whether you still need treatment with PREMPRO or PREMPHASE.

### **What are the possible side effects of PREMPRO or PREMPHASE?**

**Side effects are grouped by how serious they are and how often they happen when you are treated.**

#### **Serious, but less common side effects:**

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer
- High blood pressure
- Liver problems
- High blood sugar
- Enlargement of benign tumors of the uterus (“fibroids”)
- Mental depression

#### **Some of the warning signs of these 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
- Yellowing of the skin, eyes or nail beds

Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptoms that concern you.

**Less serious, but common side effects include:**

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps/bloating
- Nausea and vomiting
- Hair loss
- Fluid retention
- Vaginal yeast infection

These are not all the possible side effects of PREMPRO or PREMPHASE. For more information, ask your healthcare provider or pharmacist for advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## **What can I do to lower my chances of getting a serious side effect with PREMPRO or PREMPHASE?**

- Talk with your healthcare provider regularly about whether you should continue taking PREMPRO or PREMPHASE
- See your healthcare provider right away if you get vaginal bleeding while taking PREMPRO or PREMPHASE
- Have a pelvic exam, 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 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 higher chances for getting heart disease

Ask your healthcare provider for ways to lower your chances of getting heart disease.

## **General Information about the safe and effective use of PREMPRO and PREMPHASE**

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

### **Keep PREMPRO and PREMPHASE out of the reach of children.**

This leaflet provides a summary of the most important information about PREMPRO and PREMPHASE. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about PREMPRO and PREMPHASE that is written for health professionals by calling the toll free number 800-934-5556.

## **What are the ingredients in PREMPRO and PREMPHASE?**

PREMPRO contains the same conjugated estrogens found in Premarin, which are a mixture of sodium estrone sulfate and sodium equilin sulfate and other components, including sodium sulfate conjugates, 17 $\alpha$ -dihydroequilin, 17 $\alpha$ -estradiol and 17 $\beta$ -dihydroequilin. PREMPRO also contains either 1.5, 2.5, or 5 mg of medroxyprogesterone acetate.

PREMPRO 0.3 mg/1.5 mg, 0.45 mg/1.5 mg, and 0.625 mg/2.5 mg tablets also contain calcium phosphate tribasic, microcrystalline cellulose, lactose monohydrate, hypromellose, magnesium stearate, polyethylene glycol, sucrose, hydroxypropyl cellulose, Eudragit NE 30D, povidone, titanium dioxide, red iron oxide, yellow iron oxide, and black iron oxide.

PREMPRO 0.625 mg/5 mg tablets also contain calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose,

pharmaceutical glaze, polyethylene glycol, sucrose, povidone, titanium dioxide, FD&C Blue No. 2, and black iron oxide.

PREMPHASE is two separate tablets. One tablet (maroon color) is 0.625 mg of Premarin, which is a mixture of sodium estrone sulfate and sodium equilin sulfate and other components, including sodium sulfate conjugates, 17  $\alpha$ -dihydroequilin, 17  $\alpha$ -estradiol and 17  $\beta$ -dihydroequilin. The maroon tablet also contains calcium phosphate tribasic, hydroxypropyl cellulose, microcrystalline cellulose, powdered cellulose, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, sucrose, titanium dioxide, FD&C Blue No. 2, FD&C Red No. 40. The second tablet (light-blue color) contains 0.625 mg of the same ingredients as the maroon color tablet plus 5 mg of medroxyprogesterone acetate. The light-blue tablet also contains calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, sucrose, povidone, titanium dioxide, FD&C Blue No. 2, and black iron oxide.

PREMPRO therapy consists of a single tablet to be taken once daily.

**PREMPRO 0.3 mg/1.5 mg**

Blister Card - Each carton includes 1 blister card containing 28 oval, cream tablets. Each tablet contains 0.3 mg of the conjugated estrogens found in Premarin tablets and 1.5 mg of medroxyprogesterone acetate for oral administration.

**PREMPRO 0.45 mg/1.5 mg**

Blister Card - Each carton includes 1 blister card containing 28 oval, gold tablets. Each tablet contains 0.45 mg of the conjugated estrogens found in Premarin tablets and 1.5 mg of medroxyprogesterone acetate for oral administration.

**PREMPRO 0.625 mg/2.5 mg**

Blister Card - Each carton includes 1 blister card containing 28 oval, peach tablets. Each tablet contains 0.625 mg of the conjugated estrogens found in Premarin tablets and 2.5 mg of medroxyprogesterone acetate for oral administration.

**PREMPRO 0.625 mg/5 mg**

EZ DIAL<sup>®</sup> dispenser - Each carton includes 3 EZ DIAL dispensers containing 28 tablets. One EZ DIAL dispenser contains 28 oval, light-blue tablets. Each tablet contains 0.625 mg of the conjugated estrogens found in Premarin tablets and 5 mg of medroxyprogesterone acetate for oral administration.

Blister Card - Each carton includes 1 blister card containing 28 oval, light-blue tablets. Each tablet contains 0.625 mg of the conjugated estrogens found in Premarin tablets and 5 mg of medroxyprogesterone acetate for oral administration.

PREMPHASE therapy consists of two separate tablets; one maroon Premarin tablet taken daily on days 1 through 14 and one light-blue tablet taken on days 15 through 28.

Each carton includes 1 blister pack containing 28 tablets. One blister pack contains 14 oval, maroon Premarin tablets containing 0.625 mg of conjugated estrogens and 14 oval, light-blue tablets that contain 0.625 mg of the conjugated estrogens found in Premarin tablets and 5 mg of medroxyprogesterone acetate for oral administration.

The appearance of PREMPRO tablets is a trademark of Wyeth Pharmaceuticals.

The appearance of PREMARIN tablets is a trademark of Wyeth Pharmaceuticals. The appearance of the conjugated estrogens/medroxyprogesterone acetate combination tablets is a trademark.

**Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].**



This product's label may have been updated. For current package insert and further product information, please visit [www.pfizerpro.com](http://www.pfizerpro.com) or call our medical communications department toll-free at 1-800-934-5556.



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