

PATIENT INFORMATION
(Updated July 2006)

OGEN[®]
estropipate tablets, USP

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

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT OGEN (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 health care 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 health care provider should talk regularly about whether you still need treatment with OGEN.

What is OGEN?

OGEN is a medicine that contains estrogen hormones.

What is OGEN used for?

OGEN is used during and after menopause to:

- **reduce moderate or severe hot flashes.**

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 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 do not need to use estrogens. In other women, symptoms can be more severe. You and your health care provider should talk regularly about whether you still need treatment with OGEN.

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

You and your health care provider should talk regularly about whether you still need treatment with OGEN to control these problems. If you use OGEN only to treat your dryness, itching, and burning in and around your vagina, talk with your health care 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 OGEN only to prevent osteoporosis from menopause, talk with your health care provider about whether a different treatment or medicine without estrogens might be better for you. You and your health care provider should talk regularly about whether you should continue with OGEN.

Weight-bearing exercise, like walking or running, and taking calcium and vitamin D supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your health care provider before starting them.

OGEN is also used to:

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

Who should not take OGEN?

Do not start taking OGEN 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 health care provider about whether you should take OGEN.

- **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 OGEN or any of its ingredients.**

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

- **think you may be pregnant.**

Tell your health care provider:

- **if you are breastfeeding.**

The hormone in OGEN can pass into your milk.

- **about all of your medical problems.**

Your health care 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 OGEN works. OGEN 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 OGEN?

Take OGEN as directed by your health care provider. OGEN comes in three strengths. Check with your health care provider periodically to make sure you are using the appropriate dose.

1. Start at the lowest dose and talk to your health care provider about how well that dose is working for you.
2. Estrogens should be used at the lowest dose possible for your treatment only as long as needed. The lowest effective dose of OGEN has not been determined. You and your health care provider should talk regularly (for example, every 3 to 6 months) about whether you still need treatment with OGEN.

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 health care 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 OGEN. For more information, ask your health care provider or pharmacist.

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

Talk with your health care provider regularly about whether you should continue taking OGEN. If you have a uterus, talk to your health care provider about whether the addition of a progestin is right for you. See your health care provider right away if you get

vaginal bleeding while taking OGEN. Have a breast exam and mammogram (breast X-ray) every year unless your health care 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 health care provider for ways to lower your chances for getting heart disease.

General information about safe and effective use of OGEN

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

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

What are the ingredients in OGEN?

OGEN contains estropipate as the active ingredient. OGEN also contains colloidal silicon dioxide, dibasic potassium phosphate, hydrogenated vegetable oil wax, hydroxypropyl cellulose, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and tromethamine.

The color ingredients are:

OGEN .625 (yellow tablet): D&C Yellow No. 10 and FD&C Yellow No. 6.

OGEN 1.25 (peach tablet): FD&C Yellow No. 6.

OGEN 2.5 (blue tablet): FD&C Blue No. 2.



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