PATIENT INFORMATION

PROVERA®
(medroxyprogesterone acetate tablets, USP)

Read this PATIENT INFORMATION before you start taking PROVERA and read the patient information each time you refill your PROVERA prescription. 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 PROVERA (A PROGESTIN HORMONE)?

* Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (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 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 health care provider should talk regularly about whether you still need treatment with PROVERA.

What is PROVERA?

PROVERA is a medicine that contains medroxyprogesterone acetate, a progestin hormone.

What is PROVERA used for?

PROVERA is used to:

- Treat menstrual periods that have stopped or to treat abnormal uterine bleeding. Women with a uterus who are not pregnant, who stop having regular menstrual periods or who begin to have irregular menstrual periods may have a drop in their progesterone level. Talk with your health care provider about whether PROVERA is right for you.
- Reduce your chances of getting cancer of the uterus. In postmenopausal women with a uterus who use estrogens, taking progestin in combination with estrogen will reduce your chances of getting cancer of the uterus.

Who should not take PROVERA?

Do not start taking PROVERA if you:

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

  Estrogen plus progestin may increase your chance of getting certain cancers, including cancer of the breast. If you have or have had cancer, talk with your health care provider about whether you should use PROVERA.

- **Had a stroke or heart attack in the past year**
- **Currently have or have had blood clots**
- **Currently have or have had liver problems**
- **Think you may be pregnant**

  Tell you health care provider if you think that you may be pregnant or having a miscarriage. There may be an increased risk of minor birth defects in children whose mothers take this drug during the first 4 months of pregnancy. If you take PROVERA and later find out you were pregnant when you took it, be sure to discuss this with your doctor as soon as possible.

  PROVERA should not be used as a test for pregnancy.

- **Are allergic to any of the ingredients in PROVERA**

  See the list of ingredients in PROVERA at the end of this leaflet.

Tell your health care provider:

- **If you are breastfeeding.** The hormone in PROVERA can pass into your breast 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 headaches; endometriosis (severe pelvic pain); lupus; problems with your heart, liver, thyroid, or kidneys; or if you 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 PROVERA works. PROVERA may also affect how other medicines work.
- **If you are going to have surgery or will be on bed rest.** If you are taking estrogen in addition to PROVERA, you may need to stop taking estrogen and PROVERA.

How should I take PROVERA?

Start at the lowest dose and talk to your health care provider about how well that dose is working for you. The lowest effective dose of PROVERA has not been determined. You and your health care provider should talk regularly (every 3-6 months) about the dose you are taking and whether you still need treatment with PROVERA.

1. **Absence of menstrual period:** PROVERA may be given in doses ranging from 5 to 10 mg daily for 5 to 10 days.

2. **Abnormal Uterine Bleeding:** PROVERA may be given in doses ranging from 5 to 10 mg daily for 5 to 10 days.

3. **Overgrowth of the lining of the uterus:** When used in combination with oral conjugated estrogens in postmenopausal women with a uterus, PROVERA may be given in doses ranging from 5 or 10 mg daily for 12 to 14 straight days per month.

What are the possible side effects of PROVERA?

The following side effects have been reported with the use of PROVERA alone:

- Breast tenderness
- Breast milk secretion
- Breakthrough bleeding
- Spotting (minor vaginal bleeding)
- Irregular periods
- Amenorrhea (absence of menstrual periods)
- Vaginal secretions
- Headaches
- Nervousness
- Dizziness
- Depression
- Insomnia, sleepiness, fatigue
- Premenstrual syndrome-like symptoms
- Thrombophlebitis (inflamed veins)
- Blood clot

- Itching, hives, skin rash
- Acne
- Hair loss, hair growth
- Abdominal discomfort
- Nausea
- Bloating
- Fever
- Increase in weight
- Swelling
- Changes in vision and sensitivity to contact lenses

The following side effects have been reported with the use of PROVERA with an estrogen.

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

Serious but less common side effects of estrogen include:

- **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")**

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 health care provider right away if you get any of these warning signs, or any other unusual symptom that concerns 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 PROVERA with or without estrogen. For more information, ask your health care provider or pharmacist.

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

- Talk with your health care provider regularly about whether you should continue taking PROVERA. The addition of a progestin is generally recommended for women with a uterus to reduce the chance of getting cancer of the uterus.
- See your health care provider right away if you get vaginal bleeding while taking PROVERA.
- Have a pelvic exam, breast exam and mammogram (breast X-ray) every year unless your health care 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 health care provider for ways to lower your chance of getting heart disease.

General information about safe and effective use of PROVERA

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

Keep PROVERA out of the reach of children.

This leaflet provides a summary of the most important information about PROVERA. If you would like more information, talk with your health care provider or pharmacist. You can ask for information about PROVERA that is written for health professionals. You can get more information by calling the toll-free number, 1-800-438-1985.

What are the ingredients in PROVERA?

Each PROVERA tablet for oral administration contains 2.5 mg, 5 mg or 10 mg of medroxyprogesterone acetate.

Inactive ingredients: calcium stearate, corn starch, lactose, mineral oil, sorbic acid, sucrose, talc. The 2.5 mg tablet contains FD&C Yellow No. 6.

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