PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PROVERA

Medroxyprogesterone acetate tablets USP

Read this carefully before you start taking **PROVERA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PROVERA**.

Serious Warnings and Precautions

In postmenopausal women, taking estrogen-alone who had prior surgery to remove the uterus (called a hysterectomy), there is an increased risk of:

- stroke (bleeding or blood clot in the brain), and
- deep vein thrombosis (blood clot in the deep veins of the leg or arm).

If you are taking PROVERA with estrogen medication (another female hormone), there is an increased risk of developing serious problems. This includes breast cancer, heart attack, stroke and blood clots in both lungs and large veins.

Estrogens with or without progestins (PROVERA) should:

- not be used to prevent heart disease or stroke.
- be used at the lowest effective dose and for the shortest period of time possible. You should have regular medical check-ups.

What is PROVERA used for?

PROVERA is used in women with an intact uterus:

- As a hormonal replacement therapy and are also receiving estrogen. This is to protect the endometrium from the effects of estrogen and lower the risk of endometrial cancer.
- To treat menstrual disorders due to hormonal imbalance in non-pregnant women.
- As an added treatment to relieve symptoms of endometrial cancer.

PROVERA is used in postmenopausal women:

- As an added treatment to relieve symptoms of breast cancer.

How does PROVERA work?
For menstrual problems:

PROVERA is a hormone replacement therapy (HRT) that contains a progesterone hormone (progestin). It is similar to the progesterone produced by a woman's ovaries.

When given with estrogen, PROVERA lowers the risk of developing endometrial hyperplasia (overgrowth of the uterus lining) and the risk of cancer of the uterus.

PROVERA helps to balance the effect of estrogen, for non-pregnant women, to treat menstrual problems. The endometrium (inner lining of the uterus) does not grow as much and bleeding decreases.

For cancer:

When used to treat cancer, PROVERA is thought to work two-ways: it lowers hormone release and it prevents the cancer cells from multiplying. PROVERA balances out high levels of estrogen.

What are the ingredients in PROVERA?

Medicinal ingredients: Medroxyprogesterone acetate

Non-medicinal ingredients: Calcium stearate, corn starch, lactose monohydrate, mineral oil, purified water, sucrose, talc. The 2.5 mg tablet also contains FD&C Yellow No. 6, and the 5 mg tablet also contains FD&C Blue No.2 oxide hydrate.

PROVERA comes in the following dosage forms:

Tablet; 2.5 mg, 5 mg and 10 mg

Do not use PROVERA if:

- you have liver problems;
- If you have had or have cancer of the breast or uterus, unless PROVERA is being used to treat and relieve the symptoms of these cancers;
- If you have abnormal vaginal bleeding;
- If you or think you are pregnant;
- If you have had or have any blood circulation problems, such as blood clots, stroke, blindness or migraine headaches;
- If you have had a stroke, heart attack or heart disease;
- If you are allergic to progestin or to any of the ingredients in the tablet.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROVERA. Talk about any health conditions or problems you may have, including if you:

- have a history of allergy or intolerance to any medications or other substances
- have a personal history of breast disease (including breast lumps), abnormal mammograms (breast x-rays), and/or breast biopsies, or a family history of breast cancer.
- have experienced any unusual or undiagnosed vaginal bleeding
- have a history of fibroids inside your womb or growth of womb lining outside your womb (endometriosis)
- have a history of liver disease, jaundice (yellowing of the eyes and/or skin). Your healthcare professional will monitor your liver by conducting liver function tests during treatment.
- have a history of itching related to estrogen use or during pregnancy
- have a history of migraine headache
- have a history of high blood pressure. Taking hormone replacement therapy, like PROVERA,

may cause your blood pressure to rise. Your healthcare professional will monitor your blood pressure while on treatment.

- have a personal or family history of blood clots, or a personal history of heart disease or stroke
- have a history of kidney disease
- have a history of asthma or epilepsy (seizures)
- have a history of bone disease. This includes certain metabolic conditions or cancers that can affect the levels of calcium and phosphorus in your blood.
- have been diagnosed with diabetes or at a risk of developing diabetes
- have been diagnosed with porphyria (a blood disease)
- have a history of high cholesterol or high triglycerides (fats). Your healthcare professional will test your blood during and before treatment. Your healthcare professional may need to lower the levels of fat in your blood before you start your treatment.
- are pregnant or may be pregnant
- have had a hysterectomy (surgical removal of the uterus)
- smoke
- had surgery recently or are planning to have surgery in the future
- have a history of meningioma (brain tumour)
- have depression

Other warnings you should know about:

- **Overgrowth of the lining of the uterus and cancer of the uterus:**
    - Taking estrogen-only HRT will increase your risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb (endometrial cancer).
    - If you still have your uterus, your healthcare professional will give PROVERA for a certain number of days of each month to lower the risk of endometrial hyperplasia (abnormal growth of the lining of the uterus). This will lower the risk of developing these side effects.
    - Talk to your healthcare professional about progestin therapy and risk factors for endometrial hyperplasia and endometrial cancer. You should also report any unexpected or unusual vaginal bleeding to your healthcare professional.
    - Within 7 days after stopping PROVERA treatment, you should have withdrawal bleeding. If bleeding occurs during the PROVERA treatment, talk to your healthcare professional. Your dose might need to be changed.
    - If you have had your uterus removed, you are not at risk of developing endometrial hyperplasia or endometrial cancer. Progestin therapy is not generally required in women who have had a hysterectomy (surgical removal of the uterus).

- **Breast Cancer:**
    - There is an higher risk of breast cancer in post-menopausal women taking combined estrogen plus progestin.
    - Estrogens with or without progestins should not be taken by women who have a personal history of breast cancer.
    - Talk to your healthcare professional before starting HRT if you have a family history of breast cancer or breast lumps, breast biopsies or abnormal mammograms (breast x-rays).
- **Ovarian Cancer:** Taking HRT for five years or more increases your risk of developing ovarian cancer. Ovarian cancer may develop when using HRT with estrogen alone or estrogen in combination with progestin.
- **Abnormal Blood Clotting:** Taking PROVERA with estrogen can increase your risk of developing blood clots. You should discuss risk factors for blood clots with your healthcare professional since blood clots can be life threatening or cause serious disability. Talk to your healthcare professional if:
    - you or a family member have a history of blood clots
    - you smoke
    - you are severely overweight
    - you have lupus

    The risk of blood clots also can temporarily increase:

    - as you get older
    - if you are inactive for long periods of time
    - following major surgery
- **Dementia:** Your risk of developing dementia (memory loss) is increased if you are a woman aged 65 and over taking estrogen with progestin.
- **Gallbladder Disease:** Your risk of developing gallbladder disease that requires surgery is increased when taking estrogens.
- **Meningioma (brain tumour):** Meningiomas may develop after long term use of progestins, including PROVERA. Your healthcare professional should stop PROVERA treatment if you get a meningioma.

Pregnant women: You should not take PROVERA if you are pregnant or become pregnant during treatment. PROVERA may harm your unborn baby.

Check-ups and testing: You will have regular visits with your healthcare professional, before and during your treatment. They will:

- Do a physical exam on you before you begin treatment. Your visit may include a blood pressure check, a breast exam, a Pap smear and pelvic exam. You should have a mammogram before starting treatment and at regular intervals as recommended by your healthcare professional. Your healthcare professional may recommend some blood tests.

- Do regular follow-up exams at least once a year to identify side effects associated with the use of PROVERA. Your first follow-up visit should be within 3 to 6 months of starting treatment.

- Advise you to regularly check your own breasts. Talk to your healthcare professional if you are

unsure on the technique to check your own breasts.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PROVERA:

- Medicines that are used to:
    - treat epilepsy and seizures, like barbiturates, hydantoins, carbamazepine
    - treat anxiety like meprobamates
    - treat pain and inflammation like phenylbutazone (an NSAID)
    - treat bacterial infections like rifampin;
- Aminoglutethimide, a medicine used to treat some cancers;
- Some herbal and natural products like St. John's wort, which can be bought without a prescription.

How to take PROVERA:

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Your healthcare professional will give the lowest dose of PROVERA to treat you.
- Take PROVERA by mouth, with or without food.
- Take PROVERA at the same time each day.

Usual dose:

- **Hormonal Replacement Therapy for Menopause**: 5 to 10 mg daily for 12 to 14 days.
- **Functional Menstrual Disorders due to Hormonal Imbalance:**

  Secondary amenorrhea (absence of menstrual period):

    - After ruling out pregnancy, 5 to 10 mg daily for 12 to 14 days every month.

  Dysfunctional uterine bleeding:

    - 5 to 10 mg daily for 10 to 14 days, beginning on the 12th to 16th day of the cycle. Repeat for 2 subsequent cycles or longer if needed.
- **Endometrial Cancer:** 200 mg to 400 mg daily.
- **Breast Cancer:** 400 mg daily, given in divided doses.

Your healthcare professional will monitor your health. They may interrupt, adjust or stop your dose. This may occur based on your current health, if you take certain other medications or if you have certain side effects.

Overdose:

Overdosage of PROVERA may cause:

- amenorrhea (missing your period). Irregular periods may happen for several cycles after.
- depression, tiredness, acne and hair growth on areas where you do not have hair.

If you think you, or a person you are caring for, have taken too much PROVERA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, skip the missed dose and go back to your usual dosing time. Do not take two doses at the same time.

What are possible side effects from using PROVERA?

These are not all the possible side effects you may have when taking PROVERA. If you experience any side effects not listed here, tell your healthcare professional.

- Breast tenderness, breast milk discharge
- Vaginal bleeding, spotting
- Irregular menstrual periods, amenorrhea (missing your period)
- Vaginal secretions;
- Headaches
- Fever
- Nervousness
- Dizziness
- Insomnia, sleepiness, fatigue
- Hard to concentrate
- Constipation, diarrhea
- Dry mouth
- Premenstrual syndrome-like symptoms
- Itching, hives, skin rash, acne
- Hair loss, hair growth
- Stomach discomfort, nausea, bloating
- Swelling
- Tremors, cramping, sweating
- Moon shaped face
- Change in weight, appetite
- Change in sex drive
- Change in blood pressure, heart rate
- Increased blood sugar levels

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Abdominal pain, nausea or vomiting		√	
Blood clot in the eye: Sudden partial or complete loss of vision			√
Breast abnormalities (including breast cancer): Breast lump		√	
Deep vein thrombosis (blood clot in the deep veins of the leg or arm): pain or swelling in the leg/inflamed vein			√
Depression: persistent sad mood			√
Heart attack, heart disease: Crushing chest pain or chest heaviness, jaw, left arm, between the shoulder blades or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat, lack of appetite, nausea, swelling in ankles, legs and feet, cough, fluid retention			**Ö**
Jaundice: yellowing of the skin or eyes, dark urine, light coloured stool, itching all over your body			√
Pulmonary embolism (blood clot in the lung): sharp pain in the chest, coughing blood or sudden shortness of breath			√
Stroke (bleeding or blood clot in the brain): Sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech or weakness or numbness in an arm or leg			√

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Vaginal bleeding changes: Unexpected vaginal bleeding, increased or decreased menstrual bleeding, spotting, infrequent periods or absence of bleeding		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15°C-30°C). Keep out of reach and sight of children.

If you want more information about PROVERA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.pfizer.ca or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

Last Revised FEB 17, 2025 (L3: FEB 18, 2025)