

PROVERA[®] TABLET

Medroxyprogesterone acetate (5 mg, 10 mg)

PLD Title	: Medroxyprogesterone acetate (PROVERA)
PLD Date	: 10 January 2020
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	: To update PRH address
	: To update serial number
	: PfLEET Number 2020-0057572 (S2): To address BOH comments
	: To remove phone number for reporting side effects

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What is in this leaflet

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What PROVERA is used for

PROVERA is used to:

- Treat absence of menstrual period or to treat abnormal bleeding due to hormonal imbalance in the absence of underlying condition, such as fibroids or uterine cancer.
- Prevent thickening of the inner lining of the uterus (endometrial hyperplasia) in postmenopausal women with a uterus who use estrogen tablets.

How PROVERA works

PROVERA tablets contain the active substance medroxyprogesterone acetate, which belong to a group of medicines called 'progestogens. Progestogens are similar to the natural female hormone, progesterone that helps to regulate ovulation (the release of an egg from ovary) and menstrual periods. Progesterone also helps to prepare the womb lining for pregnancy and shed the lining each month when pregnancy does not occur.

Before you use PROVERA

- When you must not use it

Do not start taking PROVERA if you:

- have undiagnosed vaginal bleeding
- currently have or suspected to have certain estrogen or progesterone dependent cancers
- known, suspected, or history of breast cancer
- have now or have had in the past blood clots forming in your arteries (arterial thrombosis), such as stroke or heart attack
- are pregnant or think you might be pregnant

- have now or have had in the past blood clots forming in your veins (venous thrombosis)
- have now or have had in the past blockade in the blood vessel (artery) preventing blood flow to the lungs.
- have any known liver problems
- are allergic to medroxyprogesterone acetate or to any of the other ingredients in PROVERA

Pregnancy and lactation

Tell your doctor if you are pregnant; think that you may be pregnant or trying to get pregnant. If you take PROVERA and later find out you are pregnant, be sure to discuss this with your doctor as soon as possible. PROVERA must not be taken if you are pregnant as hormonal medicines can affect the development of the baby (can cause deformations in the genital organs). It is important to use another method of contraception (e.g. a condom) while taking PROVERA, as it is not a contraceptive.

PROVERA should not be used if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking PROVERA tablets if you have or previously had any of the following conditions:

- asthma
- diabetes
- fits
- migraine
- porphyria (build-up of certain chemicals in body)
- systemic lupus erythematosus (SLE) (an allergic condition which causes joint pain, skin rashes and fever)
- liver problems
- hypoparathyroidism (decreased secretion or activity of parathyroid hormone)
- fluid retention
- heart problems
- kidney problems

- yellowing of the skin, eyes or nail beds associated with past estrogen use or with pregnancy
- high level of certain type of fat (triglyceride) in the blood
- high blood pressure
- tobacco use
- obesity
- personal history or family history of venous thromboembolism (blood clot in a blood vessel called veins)
- going to have surgery or will be on bed rest

If you are already in menopause and are taking PROVERA along with other medicines containing estrogen, there is an increased chance of getting blood clot in your blood vessels (deep vein thrombosis), blockage of blood vessel to the lungs (pulmonary embolism), stroke, heart attack and decline in memory or thinking skill (dementia).

The use of estrogen plus progesterone has been reported to increase the risk of breast cancer and ovarian cancer.

Estrogen therapy alone without progesterone increases the risk of endometrial cancer.

Contact your doctor right away if you experience a sudden loss of vision, vision changes, or a migraine headache.

Let your doctor know if you experience abnormal vaginal bleeding.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without prescription from a pharmacy, supermarket or health food shop.

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How to use PROVERA

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

For the absence of menstrual bleeding: Your doctor will suggest to take PROVERA in the range of 5 or 10 mg daily for 5 to 10 days. In some cases, your doctor may prescribe oestrogen to be taken at the same time with 10mg of Provera for 10 days. For absence of menstrual bleeding, the therapy can be started at any time. You may experience bleeding like period (breakthrough bleeding) 3 to 7 days after you stop taking the tablets.

For abnormal uterine bleeding due to hormonal imbalance: Your doctor will suggest to take PROVERA in the range of 5 or 10 mg daily for 5 to 10 days. In some cases, your doctor may prescribe estrogen to be taken at the same time with 10 mg of PROVERA for 10 days, starting from the 16th day of the menstrual cycle. You may experience bleeding like period (breakthrough bleeding) 3 to 7 days after you stop taking the tablets.

Overgrowth of the lining of the uterus: When used in combination with oral conjugated estrogens in postmenopausal women with a uterus, your doctor will suggest to take PROVERA in the range of 5 or 10 mg daily for 12 to 14 consecutive days per month starting from the 1st day or 16th day of cycle. Your doctor may perform clinical monitoring every 3 to 6 months to re-evaluate the treatment regimen. For women with uterus, diagnostic procedures such as endometrial sampling may be performed when deemed necessary by your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking PROVERA for as long as your doctor recommends.

- If you forget to take it

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times. Consult your doctor or pharmacist on what you should do if you missed a dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else have taken too much of this medicine. Do this even if there are no signs of discomfort. You may need urgent medical attention. Taking too many PROVERA tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness, fatigue and fake period.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking PROVERA.

Tell your doctor immediately if you are pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give PROVERA to other people, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

No effect on the ability to drive or use machines has been seen with PROVERA.

Side effects

Like all medicines, PROVERA can cause side effects, although not everybody gets them.

Side effects in women who do not take concomitant oestrogen:

- Irregular periods, change in menstrual flow, breakthrough bleeding, spotting (minor vaginal bleeding), absence of menstrual period, changes in vagina and vaginal secretions.
- Breast tenderness, breast pain and Breast milk secretion
- Inflammation of blood vessels in legs and lungs
- Nausea, liver disease
- Sensitivity reactions (itching, swelling, generalized rash, acne, loss of hair and abnormal hair growth on face and body)
- Changes in vision
- Depression, lack of sleep, drowsiness, dizziness, headache, nervousness
- Allergic reactions (swelling, rash, change in weight (increase or decrease), fever, fluid retention, tiredness, prediabetes

Side effects in women who take concomitant oestrogens:

- Irregular periods, pelvic pain, fungal infection of the vagina, vaginal secretion, inflammation of vagina, ovarian cancer, thickening of the uterus lining, cancer of the uterus.
- Breast tenderness and enlargement, breast pain, breast milk secretion, breast cancer.
- Inflammation of the blood vessels in legs and lungs, heart attack, blockage

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- of blood flow to the brain, increase in blood pressure.
- Nausea, vomiting, abdominal discomfort, bloating, liver disease, inflammation of the pancreas, liver cancer
 - Brown patches on skin, rash, red lumps on body, bleeding from damaged blood vessels, loss of scalp hair, abnormal hair growth on face and body.
 - Blockage of eye veins, intolerance to contact lenses.
 - Headache, migraine, dizziness, depression, abnormal body movement disorder, nervousness, mood disturbances, irritability, fainting, loss of memory.
 - Increase or decrease in weight, increased levels of blood sugar, worsening of skin and nervous system diseases, joint pain, leg cramps, reduced sex desire, swelling, allergic reactions, decreased levels of calcium, asthma, increased body fats.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PROVERA

- Storage

PROVERA tablets should not be used after the expiry date printed on the outer carton.

Store below 30°C

As with all medicines, keep the tablets out of the sight and reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These

measures will help to protect the environment.

Product Description

- What it looks like

PROVERA 5 mg: Pale blue, round, convex tablets scored on one side and imprinted "PROVERA 5" on the other side.

PROVERA 10 mg: White, round, convex tablets scored on one side and imprinted "PROVERA 10" on the other side.

- Ingredients

- Active ingredient

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

- Inactive ingredients

Calcium stearate, corn starch, lactose monohydrate, mineral oil, sucrose, talc FD&C Blue No.2 aluminum oxide hydrate (only 5 mg).

- MAL numbers

Provera 5 mg MAL06051306AZ
Provera 10 mg MAL20000997AZ

Manufacturer

Pfizer Italia S.r.l.,
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Under the authority of
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Product Registration Holder

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