

PROVERA® / PROVERA HD®

Medroxyprogesterone acetate tablets 2.5mg, 5mg, 10mg, 100 mg, 200 mg tablets

What is in this leaflet

This leaflet answers some common questions about PROVERA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PROVERA against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with your medicine.

You may need to read it again.

What PROVERA is used for

PROVERA is a progestogen which comes from progesterone, a natural sex hormone. PROVERA works in a similar way to progesterone.

PROVERA is used to treat:

- endometriosis – a condition in which tissue similar to the lining of the uterus (womb) grows outside the uterus, causing pain and bleeding. PROVERA helps to stop the growth of this tissue
- amenorrhoea (a lack of menstrual periods) not due to pregnancy. PROVERA with or without an estrogen helps to re-establish a regular menstrual cycle
- abnormal bleeding from the uterus, when the lining of the uterus breaks down during the menstrual cycle rather than at the end resulting in vaginal spotting or bleeding. PROVERA helps to re-

establish a regular menstrual cycle

- certain types of cancer including cancer of the breast, kidney and endometrium (the lining of the womb).

PROVERA, in combination with an estrogen containing medicine, is used to relieve symptoms of menopause in women with an intact uterus. This is called menopausal hormone therapy (MHT) (previously known as hormone replacement therapy (HRT)). PROVERA is used to protect the lining of the uterus while the estrogens relieve the symptoms of menopause. PROVERA is not suitable as a MHT treatment in women who have undergone a hysterectomy.

Your doctor may have prescribed PROVERA for another purpose. Ask your doctor or pharmacist if you have any questions about why PROVERA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take PROVERA

When you must not take it

Do not take PROVERA if you have an allergy to medroxyprogesterone acetate or any of the ingredients in PROVERA listed at the end of this leaflet.

Do not take PROVERA if you have or have had any of the following medical conditions:

- a stroke, blood clots or pulmonary embolism
- severe liver problems
- unusual or irregular vaginal bleeding or blood in your urine

that has not been diagnosed by your doctor

- breast cancer or breast lumps not diagnosed by your doctor
- bleeding or discharge from your nipples
- miscarriage
- cancer of the womb or ovary
- uncontrolled high blood pressure.

Do not take PROVERA if you are pregnant or intend to become pregnant.

PROVERA may affect your developing baby if you take it during pregnancy.

Do not take PROVERA if the packaging is torn or shows signs of tampering. Do not take PROVERA after the expiry date (EXP) printed on the pack.

If you are not sure whether you should start taking PROVERA, contact your doctor.

Before you start to take it

You must tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Before prescribing PROVERA for you, your doctor may conduct a physical examination which may include breast examinations or a mammogram and a Pap smear.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- kidney problems
- migraine
- brain and/or spinal cord tumour or abnormal growths
- epilepsy

- asthma
- diabetes
- depression
- unusual or irregular vaginal bleeding
- genital or breast cancer
- bone disease or a family history of bone disease, such as brittle bones (osteoporosis)
- vision problems
- fluid retention issues.

Talk to your doctor about how to avoid these diseases.

Clinical studies suggest a slightly increased risk of developing ovarian cancer when using PROVERA combined with an estrogen containing medicine to relieve symptoms of menopause in women with an intact uterus.

If you have any concerns about this, please discuss it with your doctor.

While the effect of PROVERA on the amount of calcium stored in your bones is unknown, clinical studies have shown that use of other products with the same active ingredient as PROVERA (e.g., DEPO-PROVERA) may result in a decrease in the amount of calcium stored in your bones. This could increase your risk of developing brittle bones (osteoporosis), which can lead to bone breakages in later life.

Talk to your doctor if you have any concerns over the risk of developing osteoporosis.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may interfere with PROVERA. These include aminoglutethimide, a medicine used to treat breast cancer. This medicine may affect how well PROVERA works. You may need different amounts of your medicine or you may need to take different

medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking PROVERA.

How to take PROVERA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much PROVERA to take. This will vary depending on the condition for which you are being treated. PROVERA should be used at the lowest effective dose to treat your condition.

Your doctor may tell you to take PROVERA every day or in repeating cycles with a break in between.

Endometriosis - the recommended dose is 10 mg of PROVERA three times a day for 90 days starting on the first day of your menstrual cycle.

Amenorrhoea - the recommended dose is 2.5 to 10 mg daily for 10 days.

Abnormal uterine bleeding - the recommended dose is 2.5 to 10 mg daily for 5 to 10 days. Treatment is usually repeated for two-three cycles in a row.

Your doctor may also ask you to take a medicine containing estrogens together with PROVERA tablets.

Menopause symptoms together with an estrogen containing medicine - the recommended dose is 10 to 20 mg per day for at least 10 to 14 days of each cycle, or 2.5 mg to 5 mg per day

continuously for 28 days of each cycle.

Kidney and endometrial cancer - the recommended daily dose is 100 – 600 mg.

Breast cancer - the recommended daily dose is 400 mg to 1500 mg.

How to take PROVERA

Swallow the tablets whole with a full glass of water.

When to take it

Take PROVERA at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take PROVERA

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking PROVERA as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

While you are taking PROVERA

Things you must do

Take PROVERA exactly as your doctor has prescribed.

If you become pregnant while you are taking PROVERA, tell your doctor.

If you develop unexplained or persistent pains in the head, chest, stomach or legs, you should see your doctor immediately.

Tell all doctors and pharmacists who are treating you that you are taking PROVERA.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking PROVERA.

If you are going to have any laboratory tests, tell your doctor that you are taking PROVERA.

PROVERA may interfere with the results of some tests.

If you feel that PROVERA is not helping your condition, tell your doctor.

Also, tell your doctor if, for any reason, you have not taken PROVERA exactly as prescribed.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking PROVERA.

Regularly check your breasts for any lumps and have regular professional breast examination and mammograms as recommended by your doctor.

If you are taking PROVERA for prolonged periods, your doctor may also need to evaluate your bone mineral density (BMD).

Things you must not do

Do not give PROVERA to anyone else, even if they have the same condition as you.

Do not take PROVERA to treat other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how PROVERA affects you. PROVERA generally does not cause any problems with your ability to drive a car or operate machinery.

However, PROVERA may cause dizziness, drowsiness or fatigue in some people. Make sure you know how you react to PROVERA before driving a car or operating machinery.

Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while taking PROVERA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, PROVERA can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nervousness or difficulty concentrating
- increased heart rate
- trouble sleeping
- drowsiness or sleepiness
- fatigue
- depression or excitement
- dizziness

- headache
- skin conditions, such as hives, itching, rash or acne
- unusual hair loss or thinning or increased hairiness
- sweating
- irregular vaginal bleeding or spotting or unusual changes in vaginal secretions
- lack of menstrual periods
- nausea or vomiting
- unusual secretion of breast milk
- fever
- change in weight (increase or decrease)
- tremor
- constipation or diarrhoea
- dry mouth, increased thirst
- frequently urinating
- breast tenderness
- changes in sexual drive
- backache, leg cramps, muscle spasms
- changes in appetite
- fluid retention or bloating
- impotence (mainly in cancer treated patients).

Tell your doctor as soon as possible if you notice the following:

- confusion or memory loss
- lumps or change in your breasts or armpits
- irritation or dimpling of breast skin.
- redness or flaky skin in the nipple area or the breast
- yellowing of the skin or eyes
- abnormal liver function test
- changes in body fat (e.g., an increased amount of fat in the upper back, neck, breast, and trunk, and loss of fat from the legs, arms, and face).

Although these side effects are not common, they may require further medical assessment for serious

conditions, such as dementia or breast cancer.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis)
- severe headaches or changes in speech or vision
- painful swelling in the arms or legs
- swollen or tender veins
- sudden blocking of a blood vessel
- blood clots
- blood clots in the retina at the back of the eye
- chest pain or shortness of breath
- hand tremors, swelling, cramps in calves at night
- weakness or numbness in your arms or legs
- seizures
- hearing loss.

These are rare, but serious side effects. You may need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking PROVERA

Storage

Keep PROVERA in a cool, dry place where the temperature stays below 30°C.

Do not store PROVERA, or any other medicine, in a bathroom or near a sink. Do not leave it in the

car or on window sills. Heat and dampness can destroy some medicines.

Keep your PROVERA tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PROVERA or it has passed its expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

PROVERA tablets are available in 2.5 mg, 5 mg, 10 mg, 100 mg and 200 mg strengths.

PROVERA 2.5 mg tablets are orange, round and convex with one side scored and marked “U64”. The 2.5 mg tablets are available in blister packs of 30 tablets.

PROVERA 5 mg tablets are pale blue, round and convex with one side marked “U” and the other side scored and marked “286” both sides of the scoreline. The 5 mg tablets are available in blister packs of 100 tablets.

PROVERA 10 mg tablets are white, round and convex with one side scored and marked “UPJOHN 50”. The 10 mg tablets are available in blister packs of 30.

PROVERA 100 mg tablets are white, scored and marked “U467”. The 100 mg tablets are available in blister packs of 100 tablets.

PROVERA 200 mg tablets are white, scored and marked “U320”. The 200 mg tablets are available in blister packs of 30 tablets.

Ingredients

The active ingredient in PROVERA tablets is medroxyprogesterone acetate.

PROVERA 2.5 mg, 5 mg and 10 mg tablets also contain lactose, sucrose, maize starch, liquid paraffin, purified talc, calcium stearate, purified water, and the colouring agents sunset yellow FCF (2.5 mg) and indigo carmine (5 mg).

PROVERA 100 mg and 200 mg tablets also contain sodium starch glycollate, microcrystalline cellulose, maize starch, gelatin, docusate sodium, macrogol 400, sodium benzoate, isopropyl alcohol, magnesium stearate and purified water.

Supplier

Pfizer New Zealand Limited
PO Box 3998
Auckland, New Zealand.

Toll Free Number: 0800 736 363
www.pfizermedicalinformation.co.nz

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