

Provera[®]

Medroxyprogesterone acetate tablets 2.5mg, 5mg, 10mg

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 using 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:

1. 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.
2. Amenorrhoea together with an oestrogen containing medicine. Amenorrhoea is a lack of menstrual periods not due to pregnancy. Provera helps to re-establish a regular menstrual cycle.
3. Abnormal bleeding from the uterus where 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.

4. Symptoms of menopause such as hot flushes or sweating together with an oestrogen containing medicine. Provera works by protecting the lining of the uterus while taking the oestrogen treatment.

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

A complete medical and family history should be taken before the initiation of any hormone therapy.

When you must not take it

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

- blood clots in your legs
- liver problems
- unusual or irregular vaginal bleeding
- any lumps in your breast
- any bleeding or discharge from your nipples
- breast cancer
- miscarriage
- cancer of the womb or ovary.

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 are pregnant or intend to become pregnant.

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:

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
2. you are breastfeeding.
3. you have or have had any medical conditions, especially the following:
 - heart problems
 - kidney problems
 - a stroke
 - migraine
 - high blood pressure
 - epilepsy
 - asthma
 - diabetes
 - depression.

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 using Provera.

How to take Provera

Follow all directions given to you by your doctor or pharmacist carefully. Their directions may differ from the information contained in this leaflet. Your doctor or pharmacist will tell you how many tablets you will need to take each day. (This depends on your condition and whether or not you are taking any other medicines).

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

How much to take, when to take it and for how long to take Provera

The dose of Provera will vary depending on the condition for which you are being treated.

For 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.

For amenorrhoea, the recommended dose is 2.5 to 10 mg daily for 10 days.

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

For symptoms of menopause together with an oestrogen containing medicine, the recommended dose is 10 to 20 mg

per day for at least 10 days of each cycle, or 2.5 mg to 5 mg per day continuously for 28 days of each cycle.

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.

If you take too much (overdose)

It is important that you do not take more Provera tablets than your doctor has prescribed. If you do take more Provera tablets than you have been prescribed, contact your doctor for advice.

If a child accidentally swallows one or more of your Provera tablets, immediately telephone your doctor or pharmacist or the National Poisons Centre (telephone 03 474 7000) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Provera

Things you must do

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 using Provera.

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.

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

- trouble sleeping
- drowsiness or sleepiness
- fatigue
- depression
- dizziness
- headache
- hives
- itching
- rash
- acne
- excessive hairiness
- unusual hair loss or thinning
- sweating
- irregular vaginal bleeding or spotting
- lack of menstrual periods
- nausea
- breast tenderness
- unusual secretion of breast milk
- unusual changes in vaginal secretions
- very high fever
- weight gain.

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

- sudden 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)
- unexplained or persistent pains in the head, chest, stomach or legs.

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 using 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 using 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, 5 and 10 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.

Ingredients

The active ingredient in Provera tablets is medroxyprogesterone acetate.

Provera tablets also contain lactose, sucrose, maize-starch, liquid paraffin, purified talc, calcium stearate, purified water, and the colouring agents sunset yellow FCF CI15985 (2.5 mg) and indigo carmine CI73015 (5 mg).

Supplier

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This leaflet was prepared in August 2005.

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