

PROVERA® High Dose Tablets

Medroxyprogesterone acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROVERA high dose tablets. 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 contains a progestogen that comes from progesterone, a natural sex hormone. PROVERA high dose tablets are used to treat the symptoms of recurrent or metastatic cancer (cancer which has spread to other parts of the body). The types of cancer in which PROVERA high dose tablets may be of use are breast cancer, kidney cancer and endometrial cancer, which is cancer of the lining of the uterus (womb).

However, 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 or have had any of the following medical conditions unless advised otherwise by your doctor:

- a blood clotting disorder
- liver problems
- unusual or irregular vaginal bleeding
- any lumps in your breast
- any bleeding or discharge from your nipples
- high blood pressure

Do not take PROVERA if you are pregnant or intend to become pregnant during the course of treatment.

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

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 pregnant, suspect you may be pregnant or intend to become pregnant
3. you have or have had any medical conditions, especially the following:
 - heart problems

- kidney problems
- migraine
- 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 carefully all directions given to you by your doctor or pharmacist.

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

The dose will vary depending on the condition for which you are being treated. For kidney and endometrial cancer the recommended daily dose is 200 - 400 mg. For breast cancer, the recommended daily dose is 500 mg.

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 than your doctor has prescribed. If you do, contact your doctor for advice.

If a child accidentally swallows one or more of your PROVERA tablets, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), 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 have sudden onset of migraine, pain in your legs or changes in your vision while you are taking PROVERA, tell your doctor.

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

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.

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:

- pain in your legs
- swollen or tender veins
- difficulty breathing
- nervousness, confusion, loss of concentration
- trouble sleeping
- fatigue, drowsiness or sleepiness
- depression
- dizziness
- headache
- tremor
- skin conditions such as hives, itching, rash, acne
- excessive hairiness
- unusual hair loss or thinning
- sweating
- irregular vaginal bleeding or spotting
- lack of menstrual periods
- nausea, vomiting
- constipation
- diarrhoea
- dry mouth
- yellowing of the skin or eyes
- breast tenderness
- unusual secretion of breast milk
- unusual changes in vaginal secretions
- changes in sexual drive
- high fever

- weight change
- fluid retention and an increase in blood pressure

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

- 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)
- This is a rare, but serious side effect. You will 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 a windowsill.

Heat and dampness can destroy some medicines.

Keep 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 is available in 100 mg, 200 mg, 250 mg and 500 mg strengths.

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 60 tablets.

PROVERA 250 mg tablets are white, scored and marked "U403". The 250 mg tablets are available in blister packs of 60 tablets.

PROVERA 500 mg tablets are white, capsule-shaped and marked "UPJOHN 717" on one side only. The 500 mg tablets are available in blister packs of 30 tablets.

Ingredients

The active ingredient in PROVERA is medroxyprogesterone acetate.

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

Identification

PROVERA can be identified by the Australian Register Number on the box:

100 mg AUST R 12331

200 mg AUST R 12333

250 mg AUST R 12334

500 mg AUST R 12336

Supplier

PROVERA is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll free number: 1800 675 229

This leaflet was revised on 6 July 2005.

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