

Provera® HD

Medroxyprogesterone acetate 100mg and 200mg tablets

What is in this leaflet

This leaflet answers some common questions about Provera HD (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 HD tablets against the benefits they are 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 HD tablets are used for

Provera HD tablets contain a progestogen which comes from progesterone, a natural sex hormone. Provera HD 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 HD 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 HD tablets for another purpose. Ask your doctor or pharmacist if you have any questions about why Provera HD tablets have been prescribed for you.

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

Before you take Provera HD tablets

When you must not take it

Do not take Provera HD tablets if you have or have had any of the following medical conditions unless advised otherwise by your doctor:

- unusual or irregular vaginal bleeding
- any lumps in your breast
- any bleeding or discharge from your nipples
- you pass blood when you urinate.

Do not take Provera HD tablets 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 HD tablets if you are pregnant or intend to become pregnant.

Do not take Provera HD tablets if the packaging is torn or shows signs of tampering.

Do not take Provera HD tablets after the expiry date (EXP) printed on the pack.

If you are not sure whether you should start taking Provera HD tablets, 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 breast feeding.

3. you have or have had any medical conditions, especially the following:

- heart problems
- kidney problems
- migraine
- epilepsy
- asthma
- diabetes
- depression
- high blood pressure
- liver problems.

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 HD tablets. These include aminoglutethimide, a medicine used to treat breast cancer. This medicine may affect how well Provera HD tablets work. 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 HD tablets.

How to take Provera HD tablets

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

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 at least 400 mg per day.

If you forget to take Provera HD tablets

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 HD tablets 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 HD tablets than you have been prescribed. If you do take more Provera HD tablets than you have been prescribed, contact your doctor for advice.

If a child accidentally swallows one or more of your Provera HD tablets, immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, 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 HD tablets

Things you must do

If you become pregnant while you are taking Provera HD tablets, tell your doctor.

If you have sudden onset of migraine, pain in your legs or changes in your vision while you are taking Provera HD tablets, tell your doctor.

Tell all doctors and pharmacists who are treating you that you are taking Provera HD tablets.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are using Provera HD tablets.

If you feel that Provera HD tablets are not helping your condition, tell your doctor.

Tell your doctor if, for any reason, you have not taken Provera HD tablets exactly as prescribed.

Things you must not do

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

Do not take Provera HD tablets 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 HD tablets affect you. Provera HD tablets generally do not cause any problems with your ability to drive a car or operate machinery, however, they 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 HD, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Provera HD 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
- irregular vaginal bleeding or spotting
- lack of menstrual periods
- nausea
- breast tenderness
- unusual secretion of breast milk
- change in facial shape (round appearance)
- 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 HD tablets

Storage

Keep Provera HD tablets in a cool, dry place where the temperature stays below 25°C.

Do not store Provera HD tablets, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep your Provera HD 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 HD tablets or they have passed their expiry date, ask your

pharmacist what to do with any tablets left over.

Product description

What it looks like

Provera HD tablets are available in 100 and 200 mg strengths.

Provera HD 100 mg tablets are white, scored and marked "U467". The 100 mg tablets are available in blister packs of 100 tablets.

Provera HD 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 HD tablets is medroxyprogesterone acetate.

Provera HD tablets also contain sodium starch glycollate, microcrystalline cellulose, maize-starch, Byco C, docusate sodium, macrogol 400, sodium benzoate, isopropyl alcohol, magnesium stearate and purified water.

Supplier

Provera HD is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand

Toll Free Number: 0800 736 363

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