

FINIDE

Finasteride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Finide. 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 Finide against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Finide is used for

Finide is for use by men only.

Finide is used to treat a medical condition in men called benign prostatic hyperplasia or BPH. BPH is a condition

where your prostate gland (which is near your bladder) has become bigger making it more difficult for you to pass urine. This can lead to symptoms such as:

- weak or interrupted stream of urine
- feeling that you cannot empty your bladder completely
- delay before you start to pass urine
- needing to pass urine often, especially at night
- feeling that you must pass urine right away

BPH occurs only in men and is common over the age of 50 years. In some men, BPH can lead to serious problems, including urinary tract infections and the sudden inability to pass urine at all. BPH can also lead to the need for surgery such as procedures to improve the flow of urine.

The prostate gland takes years to grow. Therefore, the symptoms of BPH take a long time to develop. Finide works by slowly reducing the size of your prostate gland. This may lead to gradual improvement in your urine flow and other symptoms over several months. Finide also helps reduce the risk of developing a sudden inability to pass urine (acute urinary retention) and the need for surgery. This may happen whether or not you notice any improvement or change in your symptoms.

Your doctor may have prescribed Finide for another reason. Ask your doctor if you have any questions about why Finide has been prescribed for you.

Finide is not addictive.

Before you take Finide

When you must not take it

Do not take Finide if:

- **you have an allergy to Finide or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to Finide may include skin rash, or swelling of the lips or face.

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking Finide, talk to your doctor.

Women who are pregnant or may be pregnant must not take Finide or handle crushed or broken tablets.

If the active ingredient in Finide is absorbed after swallowing the tablet or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs. Finide tablets are coated and will prevent contact with the active ingredient during normal handling, provided the tablets are not broken or crushed.

If a pregnant woman swallows Finide or handles crushed or broken tablets, her doctor must be consulted immediately.

Do not give Finide to children or women.

The condition for which Finide is prescribed occurs only in men.

Before you start to take it

Tell your doctor if:

- 1. you have or have had any medical conditions**
- 2. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take any Finide.

Taking other medicines

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

Some medicines may affect the way other medicines work. However, Finide has not been shown to interfere with other medicines.

Driving and operating machinery

Finasteride should not affect your ability to drive or operate machinery.

How to take Finide

How much to take

Take Finide only when prescribed by your doctor.

The usual dose in men is one tablet taken once each day.

Swallow Finide with a glass of water.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take Finide once a day at about the same time each day.

This will help you to remember to take the tablets.

It does not matter if you take Finide before or after food.

How long to take it

Finide shrinks the prostate gland slowly. Therefore, you may need to take Finide for 6 months or longer to see whether it

helps you. If it does help your symptoms, you may need to take Finide every day. Continue taking Finide for as long as your doctor prescribes. If you stop taking the medicine the prostate gland is likely to grow again.

If you forget to take it

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 your tablet as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much Finide. Do this even if there are no signs of discomfort or poisoning.

While you are taking Finide

Things you must do

Go to your doctor for regular checkups, including a physical check for prostate cancer once a year if you are over 50.

While BPH is not cancer and does not lead to cancer, the two conditions can exist at the same time. Finide is used for BPH not prostate cancer.

If you are having a blood test to measure your PSA (prostate - specific antigen) levels, tell your doctor you are taking Finide.

Finide can affect the results of this test.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Finide.

Things you must not do

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Finide.

Finide helps most men with BPH, but it may have unwanted side effects in a few people. All medicines can have side

effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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:

- impotence (inability to have an erection)
- less desire for sex that continues after stopping Finide
- problems with ejaculation that continued after stopping the medication

Changes or problems with ejaculation, such as decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function)

Male infertility and/or poor quality of semen have been reported after stopping Finide.

These are the more common side effects of Finide. For the most part these have been mild. In some cases, these side effects disappeared while the patient continued to take Finide. If symptoms persisted, they usually resolved on stopping the tablets.

Tell your doctor immediately if you notice any of the following:

- breast swelling and/or tenderness
- breast lumps, pain or discharge from the nipples.
- skin rash, itchiness
- hives or nettle rash (pinkish, itchy swellings on the skin)
- testicle pain

These are uncommon side effects that have been reported with Finide.

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

- swelling of the lips or face

These may be symptoms of a serious allergic reaction to Finide, which may cause difficulty in swallowing or breathing. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Finide

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Never put the tablets in another box or container, as they might get mixed up.

Keep Finide in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least 1 1/2 metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Finide comes as a blue colored, oval shaped, biconvex, film-coated tablet with the following markings: 'FIN' on one side and '5' on the other side.

A pack contains 28 or 30 tablets.

Ingredients

Active ingredient:

- Finasteride 5 mg per tablet

Inactive ingredients:

- lactose monohydrate
- pregelatinised maize (corn) starch
- sodium starch glycolate Type A
- docusate sodium
- microcrystalline cellulose
- magnesium stearate
- Opadry O3B50899

Australian Registration Number

AUST R 161631

Sponsor

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Australia

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