

APO-Finasteride 5

Finasteride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about finasteride. 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 using this medicine 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 want to read it again.

What this medicine is used for

Finasteride is for use by men only.

Finasteride is used to treat a medical condition in men called benign prostatic hyperplasia (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
- a 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. The prostate gland takes years to grow. Therefore, the symptoms of BPH take a long time to develop. In some men, BPH can lead to serious problems, including urinary tract infections and the sudden inability to pass urine at all (acute urinary retention). BPH may also require surgery to improve the flow of urine.

How it works

Finasteride 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. Finasteride also helps reduce the risk of developing a sudden inability to

pass urine and the need for surgery. This may happen whether or not you notice any improvement or change in your symptoms.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- finasteride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin

Women who are pregnant or may be pregnant must not take finasteride tablets, handle crushed or broken tablets or handle tablets with wet hands. If this occurs, her doctor must be consulted immediately.

If finasteride 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.

Whole tablets are coated to prevent contact with the active ingredient during normal handling, provided that the tablets haven't been crushed or broken.

Do not give finasteride to children or women. Finasteride is for use by men only.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

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

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

How to take this medicine

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

They may differ to the information contained in this leaflet.

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

How much to take

The usual dose is one tablet taken once each day.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Finasteride shrinks the prostate gland slowly. Therefore, you may need to take this medicine for 6 months or longer to see whether it helps you. If it does help your symptoms, you may need to take this medicine every day.

Continue taking your medicine for as long as your doctor prescribes. If you stop taking the medicine the prostate gland is likely to grow again.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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 Poisons Information Centre (telephone 13 11 26) for advice or go

to the Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor if you are about to have any blood tests.

Finasteride can affect the results of a blood test required to measure your PSA (prostate-specific antigen) levels.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

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

Things you must not do

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

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Side effects

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

Finasteride 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 but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- impotence (inability to have an erection)
- less desire for sex
- 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)

These are the more common side effects of finasteride. For the most part these have been mild. In some cases, these side

effects disappeared while the patient continued to take finasteride. If symptoms persisted, they usually resolved on stopping the tablets.

Male infertility and/or poor quality of semen have been reported infrequently. Improvement in the quality of semen has been reported after stopping finasteride.

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

- breast swelling and/or tenderness. In rare cases, male breast cancer has been reported
- breast lumps, pain or discharge from the nipples.
- skin rash, itchiness
- hives or nettle rash (pinkish, itchy swellings on the skin)
- testicle pain
- depression (feeling of severe sadness and unworthiness) including suicidal thoughts

The above list includes more serious side effects. You may need medical attention. Most of these side effects are rare.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Emergency Department at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing

- rash, itching or hives on the skin
- swelling of the lips, tongue, throat or face

These may be symptoms of a serious allergic reaction to finasteride. These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

Blue, round, biconvex, film coated tablets, marked 'F5' on one side and plain on the other.

Blister pack contains 30 tablets. AUST R 155238.

Ingredients

Each tablet contains 5 mg of finasteride as the active ingredient.

It also contains the following:

- lactose monohydrate
- microcrystalline cellulose
- pregelatinised maize starch
- lauroyl macroglycerides
- sodium starch glycollate type A
- magnesium stearate

- Opadry 03F34739 Pink

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Distributor

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