

APO-Finasteride 1

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 men with male pattern hair loss to increase hair growth on the scalp and to prevent further hair loss.

Male pattern hair loss (also known as androgenetic alopecia) is a common condition in which men experience thinning of the hair on the scalp. This often results in a receding hair line and/or balding on the top of the head. These changes typically start to occur in some men in their 20s and become more common with age.

Once hair loss has occurred over a long period of time, the hair may be permanently lost.

Male pattern hair loss is thought to be caused by a combination of family history (hereditary) and production of a male hormone, called dihydrotestosterone (DHT). Men with male pattern hair loss have more DHT in the balding part of their scalp than in other parts, resulting in increased hair loss.

How it works

Finasteride specifically lowers the levels of DHT in the scalp, helping to reverse the balding process. Finasteride does not affect hair on other parts of the body.

Men with mild to moderate, but not complete, hair loss can expect to benefit from the use of finasteride.

In women who were studied, finasteride was not effective in the treatment of hair loss.

There should be no need to change your usual hair care routine (for example, shampooing or haircuts) because you are taking finasteride.

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 it has expired or is damaged, return it to your pharmacist for disposal.

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 tablets whole with a glass of water.

When to take it

Take this medicine at about the same time each day.

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

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

How long to take it for

Male pattern hair loss is a condition that develops over a long period of time. Because it takes time for new hair to grow, you will not see immediate results. Daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further loss.

Continue taking your medicine for as long as your doctor tells you.

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

Tell your doctor and pharmacist that you are taking this medicine if you are about to be started on any new medicine.

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 male pattern hair loss, but it may have unwanted side effects in a few men. 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.

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.

This list includes the more common side effects. Mostly, these are mild:

- difficulty in achieving an erection
- less desire for sex
- decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function)

Each of these side effects occurred in less than two men in one hundred. It is important to understand that, in clinical trials, these unwanted effects disappeared in men who stopped taking finasteride, as well as in many men who continued treatment.

Problems with ejaculation that continue after stopping medication have been reported infrequently. Tell your doctor if you notice this and it worries you.

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.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- 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

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

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.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- 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
- swelling of the lips, tongue, throat or face

These may be symptoms of a serious allergic reaction to finasteride.

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

Reddish brown, round, biconvex, film coated tablets, marked 'F1' on one side and plain on the other.

Blister pack contains 28 tablets. AUST R 155233.

Ingredients

Each tablet contains 1 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

Apotex Pty Ltd

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