

APO-Finasteride 5

Contains the active ingredient finasteride

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Finasteride 5. It contains the active ingredient finasteride.

Finasteride is for use by men only.

It 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
- 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. 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.

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.

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 (acute urinary retention) and the need for surgery. This may happen whether or not you notice any improvement or change in your symptoms.

There is no evidence that this medicine is addictive.

Use in children

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 or have had any of the following:**
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to finasteride or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, 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; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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

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 the active ingredient in APO-Finasteride 5 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.

If a pregnant woman swallows finasteride tablets, handles crushed or broken tablets or handles tablets with wet hands, her doctor must be consulted immediately.

Do not give finasteride to children or women.

Finasteride is for use by men only.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions
3. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available 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. Their instructions may be different to the information in this leaflet.

How much to take

Take only when prescribed by your doctor.

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

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

How to take it

Swallow a tablet 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.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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 that you are taking this medicine if:

- you are about to be started on any new medicine
- you are about to have any blood tests

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. Finasteride 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 finasteride.

Finasteride can affect the results of this test.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours

Possible side effects

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

Finasteride helps most men with BPH, but it may have unwanted side effects in a few people.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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:

- 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)

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
- Depressions (feeling of severe sadness and unworthiness)

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and 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.

- swelling of the lips, tongue, throat or face

These may be symptoms of a serious allergic reaction to finasteride, which may cause difficulty in swallowing or breathing.

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

Allergic reactions

If you think you are having an allergic reaction to finasteride, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

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

If you take your medicine out of its original packaging 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Finasteride 5 looks like

APO-Finasteride 5 comes as a blue, round, biconvex, film coated tablets, marked 'F5' on one side and plain on the other.

A pack contains 30 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- Lactose monohydrate
- Microcrystalline cellulose
- Pregelatinised maize starch
- Lauroyl macrogolglycerides
- Sodium starch glycolate
- Magnesium stearate
- Opadry 03F34739 Pink

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Finasteride 5 tablets (blister pack): AUST R 155238.

Supplier

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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