

FINASTA® Tablets

Finasteride (phee-NAS-ter-ride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Finasta. 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 risk of you taking Finasta against the benefits it is expected to 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 Finasta is used for

The name of your medicine is Finasta. It contains the active ingredient finasteride.

Finasta is for use by men only.

This medicine 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. Finasta 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. It 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.

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

Your doctor may have prescribed it for another reason.

There is no evidence that Finasta is addictive.

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

Before you take Finasta

When you must not take it

Do not take this medicine if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product description. Symptoms of an allergic reaction to Finasta may include skin rash, or swelling of the lips or face.
- it is past its expiry date or the packaging appears to have been tampered with. If you take this medicine after the expiry date has passed, it may not work.
- **you are a woman or a child.**

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

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

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

If the active ingredient in Finasta 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. Finasta 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 Finasta or handles crushed or broken tablets, her doctor must be consulted immediately.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, especially if they are in the same drug class as finasteride
- any other substances, including foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions.

Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect the way other medicines work. However, Finasta has not been shown to interfere with other medicines.

Driving and operating machinery

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

How to take Finasta

How much to take

The usual dose in men is one tablet taken once each day with or without food.

Swallow Finasta tablets with a glass of water (about 200mL).

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 Finasta tablets once a day at about the same time each day.

How long to take it

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

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when 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) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Finasta. Do this even if there are no signs of discomfort or poisoning.

While you are taking Finasta

Things you must do

- Always follow your doctor's instructions carefully.

- 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. Finasta 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 Finasta. Finasta can affect the results of this test.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Finasta.

Things you must not do

- Do not stop taking Finasta without your doctor's permission.
- Do not use Finasta to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Side effects

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

Finasta 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.

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

- impotence (inability to have an erection) that continues after stopping the medication
- less desire for sex that continues after stopping the medication

- problems with ejaculation that continued after stopping the medication
Changes or problems with ejaculation, such as a 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 infrequently.
Improvement in the quality of semen has been reported after stopping the medication.

These are the more common side effects of Finasta. For the most part these have been mild. In some cases, these side effects disappeared while the patient continued to take Finasta. 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
In rare cases, male breast cancer has been reported.
- breast lumps, pain or discharge from the nipples
- skin rash, itchiness
- hives or nettlerash (pinkish, itchy swellings on the skin)
- testicle pain
- depression (feelings of severe sadness and unworthiness).

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

If any of the following happen, stop taking Finasta and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

These may be symptoms of a serious allergic reaction to Finasta. 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 taking Finasta

Storage

Keep Finasta in the original packaging until you need to take it.

Store below 25°C in a dry place, out of the reach of children.

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 one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What it looks like

Finasta 5mg tablets are blue, round, film-coated tablets, plain on both sides. Available in blister packs of 30 tablets.

Ingredients

Active Ingredient

Each Finasta 5mg tablet contains 5mg finasteride.

Inactive Ingredients

Each Finasta tablet also contains:

- lactose

- microcrystalline cellulose
- povidone
- docusate sodium
- magnesium stearate
- purified talc
- sodium starch glycollate (Type A)
- hypromellose
- propylene glycol
- titanium dioxide
- indigo carmine CI 73015 (aluminium lake).

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

Supplier

Finasta is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park NSW 2113

Australia

Tel: 1800 634 500

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Australian Register Number

Finasta 5mg tablets: AUST R 127409 (blisters).