

APO-FINASTERIDE 5

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-FINASTERIDE 5?

APO-FINASTERIDE 5 contains the active ingredient finasteride. APO-FINASTERIDE 5 is used to treat a medical condition in men called benign prostatic hyperplasia or BPH.

For more information, see Section [1. Why am I using APO-FINASTERIDE 5?](#) in the full CMI.

2. What should I know before I use APO-FINASTERIDE 5?

Do not use if you have ever had an allergic reaction to APO-FINASTERIDE 5 or any of the ingredients listed at the end of the CMI.

APO-FINASTERIDE 5 is for use in men only. Do not give APO-FINASTERIDE 5 to children or women.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-FINASTERIDE 5?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-FINASTERIDE 5 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-FINASTERIDE 5?

- The dose is one tablet taken once a day.

More instructions can be found in Section [4. How do I use APO-FINASTERIDE 5?](#) in the full CMI.

5. What should I know while using APO-FINASTERIDE 5?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using APO-FINASTERIDE 5
Things you should not do	• Do not give APO-FINASTERIDE 5 to anyone else, even if they have the same condition as you
Driving or using machines	• APO-FINASTERIDE 5 should not affect your ability to drive or operate machinery.
Looking after your medicine	• Keep APO-FINASTERIDE 5 in a cool dry place away from light where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using APO-FINASTERIDE 5?](#) in the full CMI.

6. Are there any side effects?

Common side effects include impotence, less desire for sex, and problems with ejaculation that continue after stopping the medication. Serious side effects include allergic reactions, breast swelling, tenderness, lumps or pain, discharge from the nipples, skin rash/hives, testicle pain, blood in semen and depression.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-FINASTERIDE 5

Active ingredient(s): *[Finasteride]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-FINASTERIDE 5. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-FINASTERIDE 5.**

Where to find information in this leaflet:

- [1. Why am I using APO-FINASTERIDE 5?](#)
- [2. What should I know before I use APO-FINASTERIDE 5?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-FINASTERIDE 5?](#)
- [5. What should I know while using APO-FINASTERIDE 5?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-FINASTERIDE 5?

APO-FINASTERIDE 5 contains the active ingredient finasteride. APO-FINASTERIDE 5 is for use by men only.

APO-FINASTERIDE 5 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. APO-FINASTERIDE 5 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. APO-FINASTERIDE 5 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.

2. What should I know before I use APO-FINASTERIDE 5?

Warnings

Do not take APO-FINASTERIDE 5 if:

- You are allergic to APO-FINASTERIDE 5, any of the ingredients listed at the end of this leaflet
- Symptoms of an allergic reaction to APO-FINASTERIDE 5 may include skin rash, or swelling of the lips or face.
- Always check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Women who are pregnant or may be pregnant must not take APO-FINASTERIDE 5 or handle crushed or broken tablets.

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.

APO-FINASTERIDE 5 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 APO-FINASTERIDE 5 or handles crushed or broken tablets, her doctor must be consulted immediately.

Women and children

- Do not give APO-FINASTERIDE 5 to children or women.
- The condition for which APO-FINASTERIDE 5 is prescribed occurs only in men.

3. What if I am taking other medicines?

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

Some medicines may affect the way other medicines work. However, APO-FINASTERIDE 5 has not been shown to interfere with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-FINASTERIDE 5.

4. How do I use APO-FINASTERIDE 5?

How much take

- Take APO-FINASTERIDE 5 only when prescribed by your doctor.
- The usual dose in men is one tablet taken once each day.
- APO-FINASTERIDE 5 shrinks the prostate gland slowly. Therefore, you may need to take APO-FINASTERIDE 5 for 6 months or longer to see whether it helps you. If it does help your symptoms, you may need to take APO-FINASTERIDE 5 every day.
- Follow the instructions provided and use APO-FINASTERIDE 5 until your doctor tells you to stop.
- If you stop taking the medicine the prostate gland is likely to grow again.

When to take APO-FINASTERIDE 5

- Take APO-FINASTERIDE 5 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 APO-FINASTERIDE 5 before or after food.

How to take APO-FINASTERIDE 5

- Swallow APO-FINASTERIDE 5 with a glass of water.

If you forget to take APO-FINASTERIDE 5

APO-FINASTERIDE 5 should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet 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 that you missed.

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

If you take too much APO-FINASTERIDE 5

If you think that you or anyone else has used too much APO-FINASTERIDE 5, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-FINASTERIDE 5?

Things you should 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. APO-FINASTERIDE 5 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 APO-FINASTERIDE 5.

APO-FINASTERIDE 5 can affect the results of this test.

Remind any doctor, dentist or pharmacist you visit that APO-FINASTERIDE 5.

Things you should not do

- Do not give APO-FINASTERIDE 5 to anyone else, even if they have the same condition as you.

Driving or using machines

- APO-FINASTERIDE 5 should not affect your ability to drive or operate machinery. Looking after your medicine
- Keep APO-FINASTERIDE 5 in a cool dry place away from light where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them.
- Never put the tablets in another box or container, as they might get mixed up.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• impotence (inability to have an erection) that continues after stopping APO-FINASTERIDE 5 • less desire for sex that continues after stopping APO-FINASTERIDE 5 • 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 infrequently. Improvement in the quality of semen has been reported after stopping APO-FINASTERIDE 5. • In some cases, these side effects disappeared while the patient continued to take APO-FINASTERIDE 5. If symptoms persisted, they usually resolved on stopping the tablets.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• swelling of the lips, tongue, throat or face • These may be symptoms of a serious allergic reaction to APO-FINASTERIDE 5, which may cause difficulty in swallowing or breathing.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
• 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 • blood in semen • depressions (feelings of severe sadness and unworthiness) including suicidal thoughts	Tell your doctor immediately if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-FINASTERIDE 5 contains

Active ingredient (main ingredient)	finasteride
Other ingredients (inactive ingredients)	• Lactose monohydrate • Microcrystalline cellulose • Pregelatinised starch • Lauroyl macroglycerides • Sodium starch glycolate type A • Magnesium stearate • Opadry 03F20404 Blue
Potential allergens	APO-FINASTERIDE 5 does not contain gluten, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

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. (Aust R 155238)

Blister pack contains 30 tablets.

Who distributes APO-FINASTERIDE 5

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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