

APO-FINASTERIDE 1

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 1?

APO-FINASTERIDE 1 contains the active ingredient finasteride. APO-FINASTERIDE 1 is used to treat men with male pattern hair loss to increase hair growth on the scalp and to prevent further hair loss.

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

2. What should I know before I use APO-FINASTERIDE 1?

Do not use if you have ever had an allergic reaction to APO-FINASTERIDE 1 or any of the ingredients listed at the end of the CMI.

APO-FINASTERIDE 1 is for use in men only. Do not give APO-FINASTERIDE 1 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 1?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-FINASTERIDE 1 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 1?

- The dose is one tablet taken once each day.

More instructions can be found in Section [4. How do I use APO-FINASTERIDE 1?](#) in the full CMI.

5. What should I know while using APO-FINASTERIDE 1?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-FINASTERIDE 1.
Things you should not do	<ul style="list-style-type: none">• Do not give APO-FINASTERIDE 1 to anyone else, even if they have the same condition as you
Driving or using machines	<ul style="list-style-type: none">• APO-FINASTERIDE 1 should not affect your ability to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-FINASTERIDE 1 in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects include difficulty achieving an erection or less desire for sex, that continues after stopping APO-FINASTERIDE 1. Serious side effects include allergic reactions, breast swelling, tenderness, lumps or pain, discharge from the nipples, male breast cancer, hives or nettle rash, skin rash or itchiness, testicle pain, blood in the 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 1

Active ingredient(s): *[Finasteride]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-FINASTERIDE 1. **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 1.**

Where to find information in this leaflet:

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

1. Why am I using APO-FINASTERIDE 1?

APO-FINASTERIDE 1 contains the active ingredient finasteride. APO-FINASTERIDE 1 is for use by men only.

APO-FINASTERIDE 1 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 (heredity) and production of a particular 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 APO-FINASTERIDE 1 works

APO-FINASTERIDE 1 specifically lowers the levels of DHT in the scalp, thus helping to reverse the balding process.

APO-FINASTERIDE 1 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 APO-FINASTERIDE 1. In women who were studied, APO-FINASTERIDE 1 was not effective in the treatment of hair loss (androgenetic alopecia).

There should be no need to change your usual hair care routine (for example, shampooing or haircuts) because you are taking APO-FINASTERIDE 1.

2. What should I know before I use APO-FINASTERIDE 1?

Warnings

Do not take APO-FINASTERIDE 1 if:

- You are allergic to finasteride, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction to APO-FINASTERIDE 1 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 1, handle crushed or broken tablets or handle tablets with wet hands.

If the active ingredient in APO-FINASTERIDE 1 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 APO-FINASTERIDE 1, handles crushed or broken tablets or handles tablets with wet hands, her doctor must be consulted immediately.

Women and children

- Do not give APO-FINASTERIDE 1 to children or women.
- APO-FINASTERIDE 1 is for use by men only.

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 1 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 1.

4. How do I use APO-FINASTERIDE 1?

How much to take

- **Take APO-FINASTERIDE 1 only when prescribed by your doctor.**
- The dose is one tablet taken once each day.
- APO-FINASTERIDE 1 will not work faster or better if you take it more than once a day.
- 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. In general, daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further loss.
- Follow the instructions provided and use APO-FINASTERIDE 1 until your doctor tells you to stop.
- If you stop taking the tablets your hair loss is likely to resume.

When to take APO-FINASTERIDE 1

It does not matter if you take APO-FINASTERIDE 1 before or after food.

How to take APO-FINASTERIDE 1

- Swallow APO-FINASTERIDE 1 with a glass of water.

If you forget to take APO-FINASTERIDE 1

APO-FINASTERIDE 1 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 use too much APO-FINASTERIDE 1

If you think that you have used too much APO-FINASTERIDE 1, 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 1?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using APO-FINASTERIDE 1.

Things you must not do

Do not give APO-FINASTERIDE 1 to anyone else, even if they have the same condition as you.

Driving or using machines

APO-FINASTERIDE 1 should not affect your ability to drive or operate machinery.

Looking after your medicine

- Keep APO-FINASTERIDE 1 in a cool dry place 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
<ul style="list-style-type: none">• difficulty in achieving an erection that continues after stopping APO-FINASTERIDE 1• less desire for sex that continued after stopping APO-FINASTERIDE 1• decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function). <p>It is important to understand that, in clinical trials, these unwanted effects</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>disappeared in men who stopped taking APO-FINASTERIDE 1, as well as in many men who continued treatment.</p> <p>Problems with ejaculation that continue after stopping medication have been reported infrequently.</p> <ul style="list-style-type: none"> • 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 1. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the lips, tongue, throat or face <p>These may be symptoms of a serious allergic reaction to APO-FINASTERIDE 1, which may cause difficulty in swallowing or breathing.</p>	<p>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.</p> <p>You may need urgent medical attention.</p>
<ul style="list-style-type: none"> • 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 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

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 1 contains

Active ingredient (main ingredient)	finasteride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • Microcrystalline cellulose • Pregelatinised maize starch • Lauroyl macroglycerides • Sodium starch glycolate type A • Magnesium stearate • Opadry 03F34739 Pink
Potential allergens	APO-FINASTERIDE 1 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 1 looks like

APO-FINASTERIDE 1 comes as a reddish brown, round, biconvex, film coated tablets, marked 'F1' on one side and plain on the other. (Aust R 155233).

Blister pack contains 28 tablets.

Who distributes APO-FINASTERIDE 1

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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