

Consumer Medicine Information

PROFAL

Finasteride 1mg Tablet

What is in this leaflet

This leaflet answers some common questions about Profal. 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 taking Profal 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 need to read it again.

What PROFAL is used for

Profal is for use by men only.

Profal 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 Profal works

Profal specifically lowers the levels of DHT in the scalp, thus helping to reverse the balding process.

Profal 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 Profal.

In women who were studied finasteride 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 Profal .

Profal is not addictive.

Before you take PROFAL

When you must not take it

Do not take Profal if:

- you have an allergy to finasteride or any of the ingredients listed at the end of this leaflet.
Symptoms of an allergic reaction to finasteride may include skin rash or swelling of the lips or face.
- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed.
If you take this medicine after the expiry date has passed, it may not work.

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

Women who are pregnant or may be pregnant must not take Profal, handle crushed or broken tablets or handle tablets with wet hands.

If the active ingredient in 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. If a pregnant woman swallows Profal, handles crushed or broken tablets or handles tablets with wet hands, her doctor must be consulted immediately.

Do not give Profal to children or women.
Profal is for use by men only.

Before you start to take it

Tell your doctor if:

- you have or have had any medical conditions.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any Profal tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy 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 PROFAL

How much to take

Take Profal only when prescribed by your doctor.

The dose is one tablet taken once each day. Finasteride will not work faster or better if you take it more than once a day.

Swallow Profal with a glass of water. It does not matter if you take Profal before or after food.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you forget to take it

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

If it is not nearly time for your next dose, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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.

How long to take it

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. Continue taking Profal for as long as your doctor prescribes.

If you stop taking it

If you stop taking the tablets your hair loss is likely to resume.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, if you think that you or anyone else may have taken too many Profal tablets. Do this even if there are no signs of discomfort or poisoning.

While you are using PROFAL

Things you must do

If you are about to be started on any new medicine tell your doctor or pharmacist that you are taking Profal .

Things you must not do

Do not give Profal tablets to anyone else, even if they have the same condition as you.

Adverse 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 as with all medicines, it may have unwanted adverse effects.

All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- 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 adverse 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.

Also, tell your doctor if you notice problems with ejaculation and it worries you.

Tell your doctor immediately if you notice any of the following:

- breast swelling and/or tenderness
- *changes in breast tissue, such as lumps, pain, enlargement or nipple discharge*
- skin rash, itchiness
- hives or nettle rash (pinkish, itchy swellings on the skin)
- depression
- testicle pain.
- palpitation

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

Tell your doctor immediately or go to accident and emergency at your nearest hospital, if the following happens:

- swelling of the lips or face.

These may be symptoms of a serious allergic reaction to Finasteride, which cause difficulty in swallowing and breathing. You may need urgent medical attention.

Serious adverse effects are rare.

Other adverse effects not listed above may occur in some men. Tell your doctor or pharmacist if you notice any other unwanted effects.

After using PROFAL

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Never put the tablets in another box or container, as they might get mixed up.

Keep Profal in a cool dry place where the temperature stays below 25 °C.

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

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Profal is presented as reddish brown, 7 mm, round, biconvex, film coated tablets marked 'F1' on one side and plain on the other side containing Finasteride 1 mg

A pack contains 28 tablets.

Ingredients

Active ingredient:

- Profal tablet contains finasteride 1 mg

Inactive Ingredients

Profal contains lactose monohydrate, cellulose microcrystalline(E460), pregelatinised starch, Lauroyl macrogolglycerides, sodium starch glycolate(Type A), magnesium Stearate(E572) as excipients.

Colouring agent as Opadry 03F34739 Pink.

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

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Date of Preparation

4 May 2017