

Patient information leaflet

Finasteride 0.01% with 5% or 7% Minoxidil and 0.5% Cetirizine topical solution

Do not swallow. For external use only

Read instructions carefully. Use only as directed.

This solution contains 0.01% Finasteride which is a Type 2 '5-Alpha reductase inhibitor' and Minoxidil (5% or 7% depending on what has been prescribed) which is a vasodilator. Both are scientifically proven and licensed to treat hair loss. It also contains Cetirizine.

It is used to treat male pattern hair loss. In the scalp, Finasteride lowers the levels of DHT (dihydrotestosterone) by blocking an enzyme (Type 2 alpha reductase that converts testosterone to DHT which contributes to the shortening of the growth phase of hair. Only men with mild to moderate but not complete hair loss can expect some benefit from treatment with Finasteride.

Minoxidil is a hair growth stimulator and increases blood flow to the hair roots and nourishes the hair follicle. It also encourages the stimulation of hair follicles by growth factors and to encourage cell division at the hair follicles.

Cetirizine is a prostaglandin D2 blocker and encourages hair follicle growth. Hair growth varies from person to person due to genetic factors and results are not guaranteed.

Do not use this solution if you:

- are **allergic** to Finasteride, Minoxidil, Cetirizine or any other ingredients in the solution (ask the pharmacist)
- are a **woman** (as this solution is for men)
- are already taking Finasteride or dutasteride tablets, used for a prostate problem called benign prostatic hyperplasia.

Warnings and precautions

Talk to your doctor or pharmacist if you:

- notice **any changes in your breast tissue** such as **lumps, pain, enlargement** of breast tissue or nipple discharge as they may be signs of a serious condition, such as breast cancer
- need to have a blood test called **"PSA" (prostate-specific antigen)**. Make sure you tell your doctor or pharmacist first as Finasteride may alter the results of this test. Also:

- Do not use more than the recommended dose. Your hair will **NOT** regrow any more quickly and you have an increased chance of getting side effects. If forgotten, just apply when your next dose is due.
- Do not apply to areas of the body other than the scalp.
- Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water.
- Accidental ingestion may cause serious unwanted cardiac events. Therefore keep this product out of the reach of children.

Mood alteration and depression

Mood alterations such as depressed mood, depression, anxiety and, less frequently suicidal thoughts have been reported in patients treated with Finasteride. If you experience any of these, you **must stop** Finasteride and contact your doctor.

Pregnancy and breastfeeding

- Finasteride should not be used by women.
- Women who are pregnant or may become pregnant should not handle this solution. If Finasteride is absorbed through the skin by a woman pregnant with a male foetus, the child may be born with malformed genital organs.
- If you think a pregnant woman has come into contact with Finasteride, you should consult a doctor.

There is no evidence to suggest that Finasteride affects ability to drive or use machines.

Finasteride should not be used in children.

Finasteride solution can be used with other medications. Tell your doctor or pharmacist if you are taking, have recently taken or are planning to take other medicines.

To be used as directed by your prescriber or pharmacist.

It may take 3 to 6 months for the full effect to develop. It is important to keep using Finasteride 0.01% with Minoxidil solution for as long as your prescriber tell you. If you stop using it, you are likely to lose your hair you have gained within 9-12 months.

Application of Finasteride 0.01% with Minoxidil solution.

Do not apply to any other area apart from the scalp.

Read instructions carefully.

Use only as directed by the prescriber.

Apply the solution to the dry scalp in the morning and in the evening leaving at least 8-12 hours gap between each dose. (The evening dose should be applied 1-2 hours before bedtime). Otherwise, use as directed by the prescriber.

When using the solution dispensed from the Hairology Centre for the first time, for the first week, start by using a 0.5ml dose, then on week 2, increase to 0.7ml dose, then on week 3 and onwards, increase to a 1ml maintenance dose as directed by the prescriber.

Get accurately the required dose into the dosing syringe given. Tilt the head back and release the liquid in drops on to different areas by gently tapping the plunger of the syringe. Make sure each drop of the solution coming out of the syringe is tiny to prevent excessive dripping on to the forehead. No application is required around the back and sides of the head.

You do not need to massage in the liquid and let it absorb into the scalp for a few minutes.

Do not use more than 2ml dose in a day

Do not use more than twice a day.

If you forget your dose, do not use twice the dose to make up for the missed dose. If forgotten, just apply when your next dose is due.

Clean the syringe after each use by rinsing with clean water.

While using this medication, it is recommend that you gently wash your scalp/hair regularly, at least twice a week.

Possible side effects

Although this is a topical solution with lower chances of adverse affects, like all medicines, this medicine can cause side effects, although not everyone gets them.

Stop using this solution and immediately contact a doctor if you experience any of the following symptoms of an allergic reaction:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of lips face, tongue or throat (angioedema)
- Breathing difficulties.

You should report to us and your doctor any changes in breast tissue such as lumps, pain, enlargement of breast tissue or nipple discharge as these may be signs of a serious condition.

Other possible side effects:

Localized itching, redness, irritated skin, dryness, flakey skin, contact dermatitis

Finasteride side effects (topical solution has lower incidence of side effects than tablets)

Uncommon (1 in 100)

- inability to develop or maintain an erection (impotence)
- problems with ejaculation (such as reduced amount of ejaculatory fluid, watery semen)
- less desire to have sex
- depression.

Not known (frequency cannot be estimated from available data)

- awareness of your heart beating (palpitations)
- increase in liver enzymes
- blood in semen
- testicular pain
- infertility
- persistent difficulty in having an erection, sex drive and problems with ejaculation after discontinuation of treatment
- anxiety.

Minoxidil side effects

Minoxidil can have side effects like all medicines but not everyone will be affected and they are usually mild. If you experience chest pain, stop using this medication and seek immediate help.

If you experience any of the following, stop using the medication and contact the clinic or your doctor: Low blood pressure, rapid heartbeat, faintness or dizziness, swollen hands, feet or face, shortness of breath, sudden unexplained weight gain, persistent local redness or rash.

Other effects which may occur include headaches, itching, acne rash, irritated skin, dryness, flakey skin, inflammatory skin disorders causing redness and itching, increased hair growth in unwanted areas, stomach pains, heart palpitations, muscle pain, general pain. Getting all listed side effects is unlikely and any that occur usually wear off after stopping use of the medication.

At the start of use, for some patients, Minoxidil can cause temporary initial hair shedding for the first 3 months. This is normal as some hairs in their final resting stage of their growth cycle are shed and replaced by new hair growth from beneath.

Also contains glycerine, denatured ethanol, purified water.

It is your duty to inform us of any change to your health or medication/vitamins/supplements you take.

Like all medicines, overusing this can be dangerous and it being regulated, we have to ensure that the correct dose is being used. Therefore, request for early supply before the due date may be declined resulting in sub-optimal treatment.

Storage:

Do not refrigerate and store this medication at room temperature between 18-25 degrees centigrade and protect from sunlight.

Keep container tightly closed.

Keep away from heat/sparks/open flames/hot surfaces - No smoking.

Do not use this medication after its expiry date.

If you notice any problems with your product you must inform us within 48 hours.

Please take care of your medication, as this prescription medication cannot be replaced due to patient mishandling or expiring (past its expiry date) by not being used.

Androgenetic alopecia is a continuing condition that requires ongoing treatment and inconsistent use could lead to substandard results.

Finasteride 1mg tablet is available on prescription as a licensed medication. Minoxidil is available as licensed medication over the counter in 2% and 5% strengths. However, higher strength of Minoxidil is available unlicensed if prescribed for special use according to a patient's need.

Similarly, Finasteride 0.01% with Minoxidil 5% or 7% and Cetirizine solution is available unlicensed if prescribed for special use according to a patient's need.

All Finasteride with Minoxidil solutions (unlicensed) at the Hairology Centre are prepared extemporaneously and formulated, with all elements licensed and approved by the MHRA.

The Hairology pharmacy is thoroughly regulated by the General Pharmaceutical Council whose officers inspect and monitor compliance to all standards.

Keep all medicines out of reach of children.