

## Patient information leaflet

### Finasteride 0.05% + Cetirizine 1% topical solution (Do not swallow. For external use only)

**Women of child-bearing age should not handle this medication**

Read instructions carefully. **Use only as directed.**

This solution contains 0.05% Finasteride which is a Type 2 '5-Alpha reductase inhibitor'. It also contains Cetirizine and caffeine. It is used to treat male pattern hair loss. In the scalp, Finasteride lowers the levels of DHT by blocking an enzyme (Type 2 alpha reductase) that converts testosterone to DHT which restricts hair growth contributing to the shortening of the growth phase of hair leading to hair loss. Only men with mild to moderate but not complete hair loss can expect some benefit from treatment with Finasteride. 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, 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** (*topical application has a lower rate of side effects*)

##### **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.

- Do not use more than the recommended dose. Your hair will **NOT** re-grow 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 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 pregnant woman with a male foetus, there is a small risk that 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% 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 0.05% solution**

If you are 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 1ml maintenance dose as directed by the prescriber.

Apply 1ml of the solution to the dry scalp ONCE a day. Get accurately 1ml 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.

Do not massage in the liquid and let it absorb into the scalp for a few minutes. Clean the syringe after each use by rinsing with clean water.

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.

While using this medication, we recommend that you 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, burning sensation, irritated skin, dryness, rash, flakey skin, contact dermatitis.

#### **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
- male infertility
- persistent difficulty in having an erection, sex drive and problems with ejaculation after discontinuation of treatment
- anxiety.

**Do not use this preparation if you are allergic to Finasteride, Cetirizine, Caffeine or any of the other ingredients in it.**

Also contains Caffeine, propylene glycol, denatured ethanol, purified water

If you get any side effects, stop using the medication and inform your doctor and us.

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.

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

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.

*Finasteride 1mg tablet is available on prescription as a licensed medication. However, Finasteride 0.05% + Cetirizine 1% solution is available unlicensed if prescribed for special use according to a patient's need.*

*All Finasteride special solutions from The Hairology Centre are formulated and prepared extemporaneously, with all elements licensed and approved by the MHRA.*

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

Keep all medicines out of reach of children

This medication is only available at The Hairology Centre