# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

## Finasteride 1 Unicorn, film coated tablets

Finasteride

Finasteride 1 Unicorn contains sugar (lactose)

Finasteride 1 Unicorn is essentially sodium-free

**Read all of this leaflet carefully before you start taking Finasteride 1 Unicorn**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Finasteride 1 Unicorn has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What Finasteride 1 Unicorn is and what it is used for
2. What you need to know before you take Finasteride 1 Unicorn
3. How to take Finasteride 1 Unicorn
4. Possible side effects
5. How to store Finasteride 1 Unicorn
6. Contents of the pack and other information

## 1. What Finasteride 1 Unicorn is and what it is used for

Finasteride 1 Unicorn contains finasteride. This belongs to a group of medicines called Type II 5-alpha reductase inhibitors.

Finasteride 1 Unicorn is used for the treatment of male pattern hair loss (also known as

androgenetic alopecia). Finasteride 1 Unicorn increases hair growth on the scalp and prevents further hair loss in men between the ages of 18 to 41 years.

**How does Finasteride 1 Unicorn work?**

Finasteride 1 Unicorn lowers the levels of a natural hormone called dihydrotestosterone (DHT) in the scalp. This helps to reverse the balding process, leading to an increased hair growth and prevention of further hair loss.

## 2. What you need to know before you take Finasteride 1 Unicorn

**Do not take Finasteride 1 Unicorn:**

- if you are a woman, including during pregnancy. This medicine is for men.
  Clinical trials have shown that medicines containing Finasteride do not work in women with hair loss.
- If you are a child or adolescent.
- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine listed in Section 6.
- If you are already taking finasteride or dutasteride (used for a prostate problem called benign prostatic hyperplasia (BPH)).

Do not take Finasteride 1 Unicorn if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

**Warnings and Precautions**

Talk to your doctor or pharmacist before taking Finasteride 1 Unicorn if you are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because Finasteride 1 Unicorn can affect the result of this test.

**Effects on fertility**

Infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after stopping the use of finasteride. Long-term studies on the effects of finasteride on fertility in men have not been performed.

**Breast Cancer**

See Section 4.

**Mood alterations and depression**

Mood changes such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride 1 Unicorn. If you experience any of these symptoms stop taking Finasteride 1 Unicorn and contact your doctor for further medical advice as soon as possible.

**Elderly**

Finasteride 1 Unicorn should not be used if you are elderly, as clinical studies have not been conducted in elderly men with male pattern hair loss.

**Children and adolescents**

Finasteride 1 Unicorn should not be used in children and adolescents. There are no data that proves the efficacy or safety of finasteride in children under the age of 18.

**Other medicines and Finasteride 1 Unicorn**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Finasteride 1 Unicorn does not usually affect other medicines.

- Do not take Finasteride 1 Unicorn if you are already taking finasteride or dutasteride,

(used for a prostate problem called benign prostatic hyperplasia (BPH)).

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist or other health care provider before taking this medicine.

Finasteride 1 Unicorn is for the treatment of male pattern hair loss in men only.

***Fertility***

Infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after stopping the use of finasteride (see Section 2).

***Pregnancy***

**Exposure to Finasteride 1 Unicorn (by pregnant women) – risk to male foetus:**

- If you are a woman who is pregnant or planning to become pregnant, do not touch crushed or broken Finasteride 1 Unicorn tablets (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Finasteride 1 Unicorn tablets, speak to your doctor.
- In addition, since Finasteride 1 Unicorn is present in semen, if you are male you should wear a condom or otherwise avoid exposure of female sexual partners at risk of becoming pregnant.

***Breastfeeding***

Finasteride 1 Unicorn should not be taken by women.

It is not known whether finasteride is excreted in human milk.

**Driving and using machines**

Finasteride 1 Unicorn is not likely to affect your ability to drive, use tools or machines. However it is not always possible to predict to what extent Finasteride 1 Unicorn may interfere with the daily activities of a patient, therefore do not engage in the above activities until you are aware of the measure to which Finasteride 1 Unicorn affects you.

**Finasteride 1 Unicorn contains Lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Finasteride 1 Unicorn contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

## 3. How to take Finasteride 1 Unicorn

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

There should be no need to change your usual hair care routine.

The recommended dose is one tablet each day. The tablet can be taken with or without food.

Finasteride 1 Unicorn will not work faster or better if you take it more than once a day.

It is important to take Finasteride 1 Unicorn for as long as your doctor prescribes it.

Male pattern hair loss is a condition that develops over a long period of time. In general, daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further hair loss. Finasteride 1 Unicorn will only work over the long term if you continue taking it.

Your doctor will tell you how long your treatment with Finasteride 1 Unicorn will last. Do not stop treatment early without consulting your doctor first. If you have the impression that the effect of Finasteride 1 Unicorn is too strong or too weak for you, tell your doctor or pharmacist.

**If you take more Finasteride 1 Unicorn than you should**

Call your doctor, pharmacist, poison centre or go to the nearest hospital emergency unit immediately if you think you have taken more of your tablets than you should.

**If you forget to take Finasteride 1 Unicorn**

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take Finasteride 1 Unicorn at the next regularly scheduled time. Do not take a double dose to make up for the forgotten dose.

**If you stop taking Finasteride 1 Unicorn**

It may take 3 or more months for the full effect to develop. It is important to keep taking Finasteride 1 Unicorn for as long as your doctor tells you. If you stop taking Finasteride 1 Unicorn, you are likely to lose the hair you have gained within 12 months of stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, Finasteride 1 Unicorn can cause side effects although not everybody gets them. Furthermore not all side effects reported for Finasteride 1 Unicorn are included in this leaflet. Should your general health worsen or if you experience any untoward

effects while taking Finasteride 1 Unicorn, please consult your health care provider for advice.

**Stop taking Finasteride 1 Unicorn and talk to your doctor if you experience:**

- Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking Finasteride 1 Unicorn and talk to your doctor immediately.
- Depression (feeling of severe sadness and unworthiness).

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

**Less frequent side effects**

- you may be unable to have an erection
- you may have less desire to have sex
- you may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

**Frequency unknown side effects:**

- breast swelling or tenderness
- palpitations (a noticeably rapid, strong, or irregular heartbeat)
- changes in the way your liver is working, which is seen in blood tests
- pain in the testicles
- blood in semen
- persistent difficulty having an erection after stopping treatment
- persistent decrease in sex drive after stopping treatment
- persistent problems with ejaculation after stopping treatment

- male infertility and/or poor quality of semen
- anxiety.

If any of these side effects gets serious, or if you notice any side effects not listed on this leaflet please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.

**Will the use of Finasteride 1 Unicorn affect the hair on other parts of your body?**

Finasteride 1 Unicorn does not affect hair on other parts of the body.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of Finasteride 1 Unicorn.

## 5. How to store Finasteride 1 Unicorn

- Store all medicines out of the sight and reach of children.
- Store at or below 25 °C.
- Keep the blister in the outer carton until required for use.
- Do not use this medicine after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What Finasteride 1 Unicorn contains**

- The active ingredient is finasteride.
- The other ingredients are colloidal anhydrous silica, docusate sodium, iron oxide yellow (colourant), lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose and Opadry Pink (containing hypromellose, hydroxypropyl cellulose, iron oxide red, iron oxide yellow, talc and titanium dioxide).

**What Finasteride 1 Unicorn looks like and contents of the pack**

Round, biconvex, red film coated tablets with a 6,5 mm nominal diameter.

Finasteride 1 Unicorn is packed in white or silver blister packs.

Each blister contains 10 or 14 tablets and packed into outer cartons of 30 or 28 tablets respectively.

**Holder of Certificate of Registration**

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