



## Package leaflet: Information for the user

### Oral Finasteride, Minoxidil and Biotin Combination Capsule

**Read this leaflet carefully before you start taking this medicine, it contains important information on the Oral Finasteride, Minoxidil and Biotin Combination capsule, its ingredients and how to use it. If you have any further questions, please ask your doctor or pharmacist.**

**This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 5.**

#### What is in this leaflet

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2. What you need to know before taking this medication
3. How to use the Oral Finasteride, Minoxidil and Biotin Combination Capsule
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#### 1. What is the Oral Finasteride, Minoxidil and Biotin Combination Capsule and what is it used for

Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a particular hormone, called dihydrotestosterone (DHT). DHT contributes to shortening of the growth phase of the hair and to thinning of the hair.

Finasteride and Minoxidil are the two clinically proven treatments for male pattern hair loss. The combination capsule contains 1mg Finasteride, 2.5mg Minoxidil and 50mcg Biotin to support hair strength.

Finasteride reduces the level of DHT, allowing hair to achieve its full growth potential, whilst Minoxidil is thought to revitalize shrunken hair follicles and increase hair quality.

Minoxidil has been well researched and is licensed and used to treat male pattern hair loss worldwide. Oral Minoxidil is considered a safe and alternative treatment to Topical Minoxidil for those who can't take Topical Minoxidil due to side effects such as scalp irritation/redness/itch or headaches.

For convenience, we have combined these two effective ingredients into one convenient capsule to treat male pattern hair loss. The addition of Biotin (Vitamin B7) adds essential support for hair, skin and nails.

With continued usage, these treatments can help to halt hair loss, improve hair quality, and reverse male pattern baldness.

Finasteride and Minoxidil work best on men at an early stage of hair loss with mild to moderate hair loss at the temples, at the hairline over the crown. Caught early, they can be highly successful (in up to 90%) at stopping hair loss and can reverse the process in the majority of men.

#### 2. What you need to know before taking this medication

##### Do not take the Oral Finasteride, Minoxidil and Biotin Combination Capsule if you:

- were not born as a male or if you are a woman (because this Finasteride is for men only and can potentially be harmful in pregnancy).
- are not 18 years or older.
- are allergic to Finasteride, Minoxidil, Biotin, Lactose or any of the other ingredients of this medicine (listed in section 7).
- are already taking Finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).
- are suffering from any form of hair loss that may not be caused by male pattern hair loss (such as drug treatment, chemotherapy, sudden/unexpected hair loss, or

have hair loss over your entire body).

-You have a history of pheochromocytoma

-You are on dialysis or have a history of renal failure

##### Warnings and precautions about Oral Finasteride and Oral Minoxidil

-Finasteride should not be taken by children and teenagers under the age of 18 years.

-Check with your doctor before taking your medicine if you are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). Finasteride can affect the result of this test, and your doctor will need to alter the reference range for the blood test.

-Finasteride may affect male fertility (see section 5: Possible side effects). Patients who are planning to conceive are advised to stop the medication 3 months prior to conceiving.

-Finasteride should not be taken by women. Women should avoid coming into contact with Finasteride, particularly if there is a possibility of pregnancy. There is a risk of harm to the developing male foetus if a pregnant woman comes into contact with Finasteride (through the skin or oral medication) during early pregnancy.

-Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride. If you experience any of these symptoms stop

taking Finasteride and contact your doctor for further medical advice as soon as possible.

-We do not recommend taking oral Minoxidil to treat hair loss if you have a history of a heart attack or heart failure.

-Hypertension - whilst Oral Minoxidil is used to treat hypertension at higher doses, in the interest of patient safety, we do not recommend Minoxidil 2.5mg for hair loss in these groups without specialist consultation.

-Oral Finasteride, Minoxidil and Biotin Combination Capsules may make you feel faint or dizzy, particularly when you first start treatment. If affected do not drive or operate machines.

-Oral Finasteride, Minoxidil and Biotin Combination Capsules for hair loss are not intended for female use. Minoxidil can pass into the breast milk. They should not be taken by anyone who is pregnant or breast feeding.

#### 3. How to use the Oral Finasteride, Minoxidil and Biotin Combination Capsule

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

Take one capsule daily, with water.

If you forget to take a capsule, do not take

a double dose to make up for a missed dose, just take the next dose as directed. Do not exceed the recommended dosage.

#### 4. When should you see results

It will take time to see the benefits of any hair loss treatment. Your hair grows approximately 1cm per month and any treatment will take several months before the benefits can be seen. Sometimes the first sign of the Combination Capsule working is that less hair is noticed on the pillow or falling out during the shower. As DHT is blocked, hairs start to achieve their full growth potential again and improve in colour and density. Maximal benefit can be seen from approximately 12 months.

#### 3 Months

It takes some time for changes to become visible. Some men will shed more fine hairs than normal, but this is only temporary.

#### 6 Months

Hair loss may have considerably slowed or stopped completely. Some people see signs of regrowth, primarily at the crown of the head.

#### 9 - 12 Months

As the medication continues to work, miniaturised hairs will be replaced by thicker healthier hairs which leads to a gradual improvement of hair density over time.

It is important to remember that you need to continue to use this medication to sustain the benefits that you have achieved.

If the medication is stopped, it is likely that hair loss will resume, and any benefits will be reversed over a 9 to 12 month period. If you are seeing ongoing deterioration of hair loss following 6-12 months of treatment, you may be a non-responder and it may not be beneficial to continue to use it. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 5. Possible side effects

Like all medicines, this medicine can cause side effects, although most people do not get them. Some of the side effects are temporary with continued treatment or disappear when treatment is stopped. The list of possible side effects is not exhaustive. Please speak to your doctor or pharmacist if you get any other possible side effects or have concerns about your treatment. If you are concerned about experiencing any side effects, please stop taking the medication immediately and seek medical advice.

#### Stop taking Oral Finasteride, Minoxidil and Biotin Combination Capsule and talk to your doctor if you experience:

–swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties, all of which can be a sign of an allergic reaction to any of the ingredients.

–depression (feeling of severe sadness and unworthiness).

–any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge – consult with your doctor immediately as these may be signs of a serious condition, such as breast cancer.

–swollen hands or feet, fluid retention/oedema.

–persistent redness, rash or irritation. of the scalp.

–persistent redness, rash or irritation of the skin.

–headaches, faintness or dizziness/ low blood pressure

–rapid or irregular heartbeat.

–chest pain

–sudden unexplained weight gain.

#### Sexual side effects

In patients taking oral Finasteride 1mg tablets, up to 4% of men reported sexual side effects (vs 2% taking a placebo). These side effects include:

–reduced libido.

–altered volume/consistency of semen/ejaculate during intercourse.

–erectile dysfunction.

These side effects tend to occur in the first six months of use and are usually temporary, disappearing on cessation of

treatment, although reports of some persistent side effects have been reported. There is currently little evidence on the occurrence of these side effects in topical form and it is thought that its local absorption could reduce the likelihood of their recurrence, although further clinical evaluation is needed to validate this.

#### Other side effects which may occur:

Temporary hair loss may occur during the first 2-6 weeks of use. This is likely to be as a result of a change within the growth cycle and it should stop within a couple of weeks. If this hair loss continues for longer than four weeks, stop using the product and talk to your doctor.

Application site reactions which may include itching, irritation, pain, rash, swelling, dry skin and redness on the scalp, ears or face, but can sometimes be more severe and include flaking, dermatitis, blistering, bleeding and ulceration.

#### Very common (may affect more than 1 in 10 people):

–persistent redness, rash or irritation.

#### Common (may affect more than 1 in 10 people):

–itching of the skin or rash.

–excessive hair growth.

–shortness of breath or difficulty breathing.

#### Uncommon (may affect more than 1 in 100 people):

–feeling sick (nausea).

#### Not known (frequency cannot be estimated from the available data):

–eye irritation (including itchy eyes).

–being sick (vomiting).

–changes in hair colour and/or texture.

–breast swelling or tenderness.

–pain in the testicles.

–fast or irregular heartbeat (palpitations).

–persistent difficulty having an erection after discontinuation of treatment.

–persistent decrease in sex drive after discontinuation of treatment.

–persistent problems with ejaculation after discontinuation of treatment.

–infertility has been reported in men who took Finasteride for a long time and had other risk factors that may affect fertility.

–normalisation or improvement of seminal quality has been reported after discontinuation of Finasteride. Long-term clinical studies about the effect of Finasteride on fertility in men have not been conducted.

–increase in the level of liver enzymes (as

seen in blood tests).

–anxiety, worsening of existing mood disorder.

#### 6. How to store Oral Finasteride, Minoxidil and Biotin Combination Capsule

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 7. Contents of the pack and other information

Oral Finasteride, Minoxidil and Biotin Combination Capsule comes in a white plastic bottle containing 60ml.

Other ingredients included are Microcrystalline cellulose Hydroxypropyl methyl cellulose (HPMC) capsule shell.