



## Package leaflet: Information for the user

### Topical Finasteride-Minoxidil and Tretinoin Spray

**Read this leaflet carefully before you start taking this medicine, it contains important information on Topical Finasteride-Minoxidil and Tretinoin Spray, how to use it and how to get the best results. 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 this leaflet

1. What is Topical Finasteride-Minoxidil and Tretinoin Spray and what is it used for
2. What you need to know before you take Topical Finasteride-Minoxidil and Tretinoin Spray
3. How to use Topical Finasteride-Minoxidil and Tretinoin Spray
4. When you should see results
5. Possible side effects
6. How to store Topical Finasteride-Minoxidil and Tretinoin Spray
7. Contents of the pack and other information

#### 1. What is Topical Finasteride - Minoxidil and Tretinoin Spray 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. This spray contains these medications, 0.1% Finasteride now available in topical form and 5% Minoxidil and also includes 0.01% Topical Tretinoin.

Topical Finasteride is an alternative to oral Finasteride in those who are unable to, or do not wish to take oral Finasteride, however it is not yet licensed specifically for use in male pattern hair loss in topical form. Clinical studies have shown that topical finasteride has a lower risk of systemic side effects (eg sexual dysfunction) and, as such, may be a suitable alternative to oral tablets, with promising results in efficacy when compared with oral Finasteride.

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

Tretinoin has recently emerged as a treatment for hair loss. It is a retinol (Vitamin A derivative) traditionally used to treat acne and wrinkles, it is thought to help significantly increase the efficacy of Minoxidil.

With continued usage, these treatments 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 you use Topical Finasteride-Minoxidil and Tretinoin Spray

##### Do not take Topical Finasteride-Minoxidil and Tretinoin Spray if you:

- were not born as a male or if you are a woman (because this medicine is for men only can potentially be harmful in pregnancy). It has been shown in clinical trials that Finasteride does not work in women with hair loss.
- are not 18 years or older.
- are allergic to Finasteride, Minoxidil, Tretinoin 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 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).
- are susceptible to severe scalp infections or psoriasis.

#### Warnings and precautions

- Finasteride should not be taken by children and teenagers under the age of 18 years.
- Check with your doctor or pharmacist before taking your medicine if you are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because 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 a 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.

#### 3. How to use Topical Finasteride-Minoxidil and Tretinoin Spray

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

Apply 6 pumps (1ml) to a dry scalp daily. Each bottle should last for two months. For best results, allow to dry in before applying any hair styling products such as hair gel, wax or mousse.

This medication is for external use only and should only be applied to the scalp. If you use too much solution or it comes in contact with the eyes, broken skin or the mouth, rinse with water immediately. If the solution is accidentally swallowed, please contact your healthcare provider immediately.

If you forget to take Topical Finasteride-Minoxidil and Tretinoin Spray 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 a number of months before the benefits can be seen. Sometimes the first sign of topical Finasteride-Minoxidil Tretinoin 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 once daily 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 disappeared when treatment is stopped. With topical treatments, the most common side effect is itching or irritation of the scalp. If this persists, stop using the medication and consult with your doctor.

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.

#### Stop taking Topical Finasteride-Minoxidil and Tretinoin Spray 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.
- 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.
- persistent redness, rash or irritation of the scalp.
- persistent redness, rash or irritation of the skin
- faintness or dizziness (uncommon).
- rapid or irregular heartbeat (rare).
- chest pain (rare).
- low blood pressure (not known).
- sudden unexplained weight gain (common).

#### 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 heart beat (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.

#### 6. How to store Topical Finasteride-Minoxidil and Tretinoin Spray

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.

Store this medicinal product between 15-25°C.

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

Topical Finasteride-Minoxidil and Tretinoin Spray comes in a white plastic bottle containing 60ml. The pack also includes a spray nozzle.

Manufactured by Xeal Pharma Ltd.  
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