

DUAL ACTION

Hair Growth Spray

Finasteride 0.3% with Minoxidil 5% plus Tretinoin 0.01%

High strength, once-daily application for thicker, longer, more visible hair

Patient Information Leaflet

Read this leaflet carefully before you start using this medicine.

To purchase visit doctorfox.co.uk/hair-loss-treatments/



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1. What is Hair Growth Spray & what is it used for?

Hair Growth Spray reduces male pattern hair loss and stimulates new hair growth - resulting in thicker, longer hairs, and more visible hair coverage.

Dual Action Hair Growth Spray from Dr Fox contains Finasteride 0.3% (3mg/1mL), Minoxidil 5% (50mg/1mL), and Tretinoin 0.01% (0.1mg/1mL).

2. How it works

In the average adult male approximately 10% of the male sex hormone testosterone is converted to the more potent hormone Dihydrotestosterone (DHT). DHT is responsible for adult male characteristics including male hair thinning and hair loss. DHT affects hair follicles in a way that prevents hairs from reaching their full growth potential. Dr Fox's dual action spray works to reverse this process using the following treatments:

Finasteride reduces the conversion of testosterone to DHT, therefore less DHT reaches hair follicles and hair is allowed to reach its full growth potential. Finasteride can be taken in tablet form (orally) and

when treatment is started early enough and used continually, hair thinning/excess hair loss can be prevented in up to 90% of men. More recently treatments applied directly to the scalp (topically) have had promising results. A significant benefit of topical, compared with oral treatment, is the reduced risk of side effects (e.g. sexual dysfunction). Topical finasteride is not yet licensed to treat male pattern hair loss, but is a safe and effective alternative to oral treatment and is available on private prescription.

Minoxidil relaxes small blood vessels where it is applied to the scalp, increasing blood flow to hair follicles. Blood carries essential oxygen and nutrients which stimulate new hair growth - encouraging thicker, longer, more visible hair.

Tretinoin is a vitamin-A derivative that promotes hair growth indirectly by increasing minoxidil uptake. Minoxidil spray alone is best used twice daily, but combined with tretinoin allows minoxidil to be used once daily.

3. Who can use Hair Growth Spray?

- Adults (aged 18+)
- Assigned male at birth
- Affected by male pattern hair loss

Treatment works best at the mild to moderate stages of hair loss; Stages 2-5 of the Hamilton-Norwood scale (see Fig 1 on next page).

4. Hair Loss Scale (1-7)

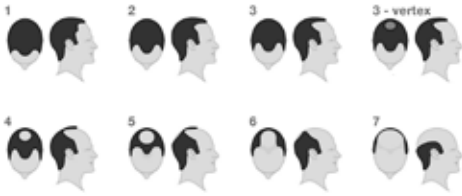


FIG 1: HAMILTON NORTON SCALE

Stage 1: No notable hair loss or recession of the hairline.

Stage 2: Often referred to as the 'adult' or 'mature' hairline. Some recession at the temples and some sparsity at the front-centre.

Stage 3 has two variants:

- Either development of deeper recession at the temples with increased sparsity at the front-centre,
- Or recession at the temples and front-centre remains at stage 2, but there is notable hair loss/sparsity at the crown (vertex).

Stage 4: Recession at the temples and front-centre is developed beyond that of stage 2 and there is hair loss/sparsity at the crown.

Stage 5: Recession at the temples and front-centre hairlines is developed beyond stage 4 along with increased hair loss/sparsity at the crown. The band of hair between these areas is still present but sparse.

Stage 6: The areas of hair loss at the front, temples, and crown have extended and merged; the band of hair crossing the crown is lost, with only sparse hair remaining.

Stage 7: The remaining hair is an (often sparse) band around the back of the head, connecting the remaining hair at the sides.

5. When can I expect to see results?

Hair on the scalp grows at approximately 1 cm per month. You can expect to see thicker, longer hair with greater scalp coverage after only a few months. Positive changes may be seen as early as 3 months, excess hair loss has usually stopped after 6 months and changes are more obvious, with maximum benefit by 1-2 years.

In the unlikely event your hair loss continues beyond 12 months treatment, with no notable increase in hair thickness or coverage, you are likely to be a non-responder and it is unlikely you will benefit from continuing treatment.

Once improved hair coverage has been achieved, continued treatment is required to maintain the

benefits. If treatment is stopped, pre-treatment appearance will likely return within 3 to 6 months.

6. How to use

1. Wash and dry your scalp.
2. Apply 12 pumps of product (2ml) to the scalp daily (suggest at night/before bed).
3. Allow the product to dry before applying any hair styling product.
4. Product does NOT need rubbing in - this will risk absorption by the skin of your hands.
5. Wash your hands thoroughly after applying.

Please note:

- For external use only.
- Apply to the scalp only.
- Do not exceed the recommended dose.
- If you forget to use the product do not double-up the following day - apply only 12 pumps per day.
- If you accidentally use too much, rinse the scalp with water.
- If the product comes in contact with your eyes, mouth, or broken skin, rinse thoroughly with water.
- If the product is swallowed, contact a healthcare provider immediately for advice.

7. Contraindications - DO NOT use if you:

- were assigned **female** at birth (finasteride does not have an adequate safety profile for use by patients where there is ANY risk of pregnancy; finasteride may affect the development of an unborn baby's genitals).
- are less than 18 years of age.
- have an allergy or hypersensitivity to finasteride, minoxidil, or tretinoin.
- are susceptible to severe scalp infections or psoriasis.
- may have hair loss due to a cause other than hereditary 'pattern' hair loss, e.g. chemotherapy or total alopecia (loss of hair over entire body). If you are unsure you should consult your GP.
- Low or high blood pressure.

8. Cautions for use

Keep away from children and animals. If swallowed, minoxidil could lead to heart toxicity.

Pregnant women and women with childbearing potential should avoid handling as finasteride may affect the development of an unborn baby's genitals.

Avoid exposure to UV light (sunlight) as tretinoin can make the skin more likely to burn.

Do not use more than the recommended dose. Treatment will not be more effective and the risk of side effects will increase.

If treatment is stopped beneficial effects will likely reverse within 6 months.

Do not apply the Hair Growth Spray if:

- your skin is broken, infected, shaved, sunburned, or inflamed, e.g. scalp eczema.
- you are having medical treatment for another condition which can cause photosensitivity (skin is more sensitive to the sun).
- using scalp dressings or bandages.

Consult your GP before using the Hair Growth Spray if you:

- have heart disease or an abnormal heart rate/rhythm. Note: oral minoxidil (tablet form) is much more potent and can be used to lower very high blood pressure. Side effects of the tablet form include: fluid retention, swelling of the feet/legs/hands, irritation of the heart sac, and a fast heart rate. As only 1-2% of the medicine is absorbed into the bloodstream when applied to the scalp, these symptoms are highly unlikely.
- have a history of urinary obstruction, or difficulty passing urine. This may be caused by an enlarged prostate gland.
- develop male breast changes: lumps, pain, enlargement, or nipple discharge. These may indicate underlying breast cancer.
- develop male breast tissue growth (gynecomastia). This can be caused by finasteride (usually in higher doses in tablet form). Early management increases the likelihood of complete reversal.
- have a PSA (prostate specific antigen) blood test planned, as topical finasteride may alter the test results.

Driving: There is no need to avoid driving.

9. Possible side effects

Side effects are much less likely when using topical rather than tablet form (oral) medication as active ingredients are delivered directly to the skin with little entering into the bloodstream:

Most common side effects:

Temporary increase in hair loss over the first 2-6 weeks of treatment is NORMAL and to be expected. This is likely due to hairs moving from the Resting phase to the Growth phase of the hair growth cycle.

Skin irritation (itching, dryness, redness) at the application site is most likely due to the alcohol base, but may be due to minoxidil or tretinoin.

Irritation usually settles with continued use - regular washing and moisturising is also beneficial. If you develop bothersome skin redness, rash, or other irritation, stop treatment. If irritation is severe or does not improve after stopping treatment, you should seek advice from a pharmacist or your GP.

Uncommon side effects:

- Feeling dizzy or faint when first starting treatment. This is likely due to the blood pressure-lowering action of minoxidil and usually subsides after short-term use. Applying treatment before bed can minimise these symptoms.
- A small amount of weight gain and or swollen feet may occur due to minoxidil causing blood vessels to dilate.
- Male breast tissue growth (gynecomastia). This is an uncommon side effect of finasteride (usually in higher doses in tablet form).
- Nausea.
- A change in mood.
- Unwanted hair growth in areas treated accidentally. Reversible over 3-6 months once product ceases to have contact with the area of skin.

Stop treatment and seek advice from your GP if you experience:

- Bothersome dizziness or feeling faint which persists after stopping treatment.
- More rapid weight gain, or weight gain associated with breathlessness.
- Persistent, bothersome nausea.
- Low mood, depression or feeling depressed (feelings of sadness and unworthiness).

Rare side effects:

Please stop treatment and seek advice from your GP urgently if you experience:

- Chest pain and or palpitations (an uncomfortable awareness of your heart beating in your chest).
- Severe depression/suicidal thoughts.
- An allergic reaction: swelling of the lips, face, tongue, or throat; breathing difficulties or difficulty swallowing.

Possible sexual side effects:

Sexual side effects are much less likely when using topical rather than tablet (oral) treatment. The following are therefore possible but unlikely:

- Reduced male fertility - advise stop treatment 3 months prior to planned conception.
- Reduced libido and erectile dysfunction.

Frequency unknown:

If you develop any of the following symptoms and are concerned, discuss with your doctor or pharmacist.

- Eye irritation.
- Vomiting.
- Pain in the testicles.
- Anxiety.

Yellow Card reporting

Worrying or unwanted side effects should be reported via the MHRA Yellow Card Scheme website www.mhra.gov.uk/yellowcard, via their app which can be downloaded from Google Play or the Apple App Store, call Freephone 0808 100 3352 (available from 10am to 2pm Monday to Friday), or fill in a paper form available from your local pharmacy.

Made in the UK

Manufactured for Dr Fox by Xeal Pharma (MS 46688), as an unlicensed medicine to treat male pattern baldness.

UK Only - not for distribution outside the UK.

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10. Further Information

Independent patient organisations including postal, telephone, helpline, and website addresses.

- **Hair loss - NHS**
www.nhs.uk/conditions/hair-loss/
- **Alopecia Society: Find a support group**
www alopecia.org.uk
- **British Hair and Nail Society: Support Group**
bhns.org.uk

Preparation

Ingredients: Minoxidil, Finasteride, Tretinoin, Glycerol, Sulphuric Acid, Industrial Methylated Spirit and Water.

60ml brown bottle with atomiser (1 month supply).

Contents are flammable - keep away from naked flames, cigarettes, and heat sources.

Store at room temperature (15-25 degrees).

Keep out of sight and reach of children.

Do not use after last day of expiry month.

Do not dispose of medicines in household water or waste. Take to a local pharmacy for safe disposal.

Information in alternative formats

For information in larger print please telephone

0117 2050198 or email info@doctorfox.co.uk

Website browsers have accessibility tools available to read aloud text from documents, for sight-impaired users.