MINOXIDIL 5%
FINASTERIDE 0.1%

Original

User information leaflet

DENSE®

Minoxidil 5%
Finasteride 0.1%

Read all of this leaflet carefully before you start taking this medicine. It contains important information that you may want to read again. If you have any further questions, ask your doctor, nurse or pharmacist or contact us at **pharmacy@densehairexperts.com.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Ask your pharmacist if you need more information or advice.

If you get any of the side effects noted within section 5, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. You must talk to a doctor if your symptoms are getting worse or do not improve after four months.

What is in this leaflet?

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

1. What Minoxidil is and what it is used for?

Minoxidil prevents hereditary hair loss in men aged 18–65 and stimulates hair growth. It also promotes the regrowth of new hair on already thinned or bald spots and thickens existing downy hair.

After application, Minoxidil penetrates the scalp and reaches the hair roots. It has not yet been possible to clarify the exact mechanism by which hair growth is stimulated. However, the active substance of Minoxidil can stop hereditary hair loss by;

- Increasing the diameter of the hair shaft.
- Stimulating growth.
- Prolonging hair growth phases.

However, it will take at least three months before you see any result. If hair roots are still present, fine light downy hair may grow back, which gets longer, denser and

darker over time. How fast hair growth starts and how many hairs grow back differs depending on the patient. Large bald spots or hair loss present for more than 10 years are less sensitive to Minoxidil.

The following illustrations show the stages of male pattern hair loss, for which it has been possible to demonstrate the effectiveness of Minoxidil.



Minoxidil must not be used in: Children and adolescents under 18 years and patients aged 65 years and older, as no efficacy and safety results from controlled studies are available in these age groups.

2. What Finasteride is and what it is used for?

Finasteride belongs to a group of medicines called Type II 5-alpha reductase inhibitors. Finasteride is used to treat early forms of male pattern hair loss – also known as androgenetic alopecia.

3. What you need to know before using this product.

Do not use if:

- You are allergic to any of the ingredients of this medicine noted with in section 7.
- Are female (this medicine if for male use only).
- Already using scalp medication
- Suffer from high blood pressure.
- Using medication to treat high blood pressure.
- Have any signs of cardiovascular disease or heart rhythm problems.
- Suffer from sudden or uneven hair loss.
- Have scalp conditions such as, but not limited to: psoriasis, sunburn, scars or burns.

Warnings and precautions

Apply this product only to a normal healthy scalp. You should not use this product if the cause of hair loss is not known or if the scalp is red, inflamed or painful.

If effects on inner organs (systemic effects) or severe skin reactions occur, the product must be discontinued.

You should stop using this product and consult your doctor if:

- You notice low blood pressure or one or more of the following symptoms appear: chest pain, faster heartbeat, weakness or dizziness, sudden and unexpected weight gain, swollen hands or feet, persistent redness or irritation of the scalp.

Accidental ingestion can cause serious effects on the cardiovascular system. Therefore, you must keep this medicine out of reach of children. Avoid breathing in spray mist.

When this treatment is stopped, the shedding of hair will occur again.

Pregnancy and breast-feeding

This product is for male use only. The active ingredients incorporated into the body can pass through breast milk.

Driving and using machines

There are no expected effects that would alter the ability to drive or operate machinery.

Finasteride contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to lactose/ sugars, contact your doctor before taking.

4. How to use this product.

Always use this medicine exactly as detailed within the leaflet or as directed by your doctor or pharmacist. Always check if you are unsure.

The product is intended for external use only. Please use on healthy, undamaged scalp and follow the instructions for use exactly at all times. Not for use in areas other than scalp.

The recommended dose Apply 1ml of product twice daily to the affected areas of the scalp (morning and evening).

The daily dose (2 x 1ml) should not be exceeded, regardless of the size of the affected skin area.

Application Spray the affected area of the scalp with a 1ml dose (5–6 spray pumps).

Massage into scalp with fingers. Avoid breathing in the mist. Wash hands thoroughly post application to avoid accidental contact with highly sensitive areas. After application, you can style your hair as normal.

Avoid moistening the scalp for 4 hours to prevent the product from being washed off.

Utilising one of our DENSE Hair Styling products for the utmost impact and style is recommended.

Duration of use

This product has a varying reaction across all patient types, its therefore recommended to use for 4 to 6 months before any effect is seen.

It is recommended to use the twice daily dose without interruption. If you use more than the recommended dose application, or application to areas other than the scalp may lead to an increased absorption on Minoxidil and Finasteride into the body.

In cases of accidental ingestion or signs of an overdose, please tell a doctor immediately. Please ensure the medication package is retained and provided to the doctor for sight of active substance volumes.

If you forget to use this product, do not apply a double dose and maintain the treatment at the recommended dosage.

To improve and maintain hair growth, continued use is required. If the treatment is stopped, hair loss will reoccur.

5. Possible side effects.

As with all medication, there is a small risk of side effects,

highlighted them below:

Contact a doctor straight away if you notice any of the following – you may require urgent medical attention.

- Swelling of the face, lips or tongue. General redness and / or itching - This could be an indication of an allergic reaction.

Very common (may affect more than 1 in 10)

- Headache.

Common (may affect up to 1 in 10)

- Itching.
- Increased hair growth in areas other than the scalp.
- Inflammatory skin reactions (including acneiform rash, skin rash).
- Shortness of breath, swollen limbs.
- Weight gain.

Uncommon (may affect up to 1 in 100)

- Dizziness and nausea.
- Erectile dysfunction and reduced labido. 1.2% in oral pill form. Even lower in topical version.

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

- Vomiting.
- Irritation.
- Increase heartbeat.
- Chest pain.
- Temporary hair loss.

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at **www.mhra.gov.uk/yellowcard.**

By reporting side affects you can help provide more information on the safety of this medication.

6. How to store.

Keep out of reach and sight of children.

Do not use past the expiry date shown on the label of the bottle marked "EXP" Do not freeze. Do not store near heater or naked flames (flammable). Store below 25°c and keep the bottle upright.

Use within 6 weeks of opening.

Do not dispose of product down the wastewater or household waste methods. Ask your pharmacist how to dispose of the product once no longer of use.

7. Contents of the product and other information

There are two active substance contained within the package: Minoxidil and Finasteride.

1ml solution contains 5% Minoxidil, 0.1% Finasteride.
Other ingredients are: Ethanol, propylene glycol and purified water

This product is cloudy.

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