MINOXIDIL 5%
DUTASTERIDE 0.1%

Sensitive (PG Free)

User information leaflet

DENSE®

Minoxidil 5%
Dutasteride 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 Dutasteride 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 Dutasteride is and what it is used for?

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

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 a female (this medicine if for male use only).
- Already using scalp medication.
- Suffer from high blood pressure.
- Using medication to treat high blood pressure.
- If you have a severe liver disease.
- 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.

If you think any of these apply to you, don't take this medicine until you have checked with your doctor.

Warnings and precautions

Dutasteride is also available in the capsule (0.5mg) form and originally used to treat men with an enlarged prostate (benign prostatic hyperplasia), a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone. The Risk of side effects of using topical Dutasteride is much lower as it is applied directly onto the scalp and it is in much lower concentration compared to the capsule alternative. The majority of risks and side effects have been cited for 0.5% Oral Dutasteride capsules.

Before taking Dutasteride
Please note these risks have been cited based on the Dutasteride capsule and the risks of these side effects are rare for the topical formulation. Dense Topical Dutasteride formulations is provided in much lower concentrations compared to the capsule equivalent thus very little medication can get into systemic circulation. It is good practice to notify you of potential side effects so you are aware. (See below and section 5).

Talk to your doctor before taking Dutasteride
Make sure Dense Pharmacy and your doctor knows about liver problems. If you have had any illness affecting your liver, you may need some additional check-ups before or while you are taking Dutasteride containing medications.

Not suitable for Women, Children or Adolescents.
Women, children and adolescents must not use this spray, because the active ingredient can be absorbed through the skin. Wash the affected area immediately with soap and water if there is any contact with the skin.

Intercourse & Fertility
It is good practice to use a condom during sexual intercourse. Dutasteride can be found in the semen of men using Dutasteride capsules. If your partner is or may be pregnant, you must avoid exposing them to your semen as Dutasteride may affect the normal development of a male baby. Dutasteride capsules have been shown to decrease sperm count, semen volume and sperm motility. This may reduce your fertility.

Blood Testing
Dutasteride capsules affects a blood test for PSA (prostate-specific antigen), which is sometimes used to detect prostate cancer. If you are having a blood test for PSA, tell your doctor that you are taking Dutasteride. It is

good practice for men taking Dutasteride to have their PSA tested regularly.

Other medicines and Dutasteride
Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines can react with Dutasteride some common interactions have been listed below.

These medicines include:

- Verapamil or Diltiazem (for high blood pressure)
- Ritonavir or Indinavir (for HIV)
- Itraconazole or Ketaconazole (for fungal infections)
- Nefazodone (an antidepressant)
- Alpha-blockers (for enlarged prostate or high blood pressure).

Tell your doctor and inform DENSE if you are taking any of the above medicines so they are aware and can advise further.

Pregnancy and breast-feeding
Pregnant or breast-feeding women must avoid contact with Dutasteride. Dutasteride can be absorbed through the skin and can affect the normal development of a male baby. This is a particular risk in the first 16 weeks of pregnancy. Use a condom during sexual intercourse. Dutasteride has been found in the semen of men taking Dutasteride capsules.

Application
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.

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

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 Dutasteride 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 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.
- Fertility changes.
- Dutasteride may cause breast enlargement and tenderness.

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 Dutasteride.

1ml solution contains 5% Minoxidil, 0.1% Dutasteride.

Other ingredients are: Hydophillic solution containing mineral salts of vegetable origin.

This product is cloudy.

Do not take Dutasteride if you are allergic to ***dutasteride, other 5-alpha reductase inhibitors, soya, peanut*** or to any of the other ingredients of this medicine.

DENSE®