Package leaflet: Information for the user
Minoxidil 5% cutaneous solution

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Minoxidil 5% cutaneous solution is and what it is used for

Minoxidil 5% cutaneous solution is a medicine for topical application to the scalp that stimulates hair growth in men aged 18–65 years with male-pattern hair loss (androgenetic alopecia) when applied to the skin.

2. What you need to know before you use Minoxidil 5% cutaneous solution

Do not use Minoxidil 5% cutaneous solution
- If you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6).
- If you are female.
- If you have high blood pressure (even if it is being treated).
- If you have inflamed, infected, irritated or painful scalp skin.
- If you have any condition that affects your scalp, including sunburn and psoriasis.
- If you have a shaved scalp.
- If you have any kind of dressing or bandage on your scalp.

Warnings and precautions
Talk to your doctor or pharmacist before using Minoxidil 5% cutaneous solution:
- If you are at all unsure whether your scalp is normal and healthy.
- If you suffer from heart disease, including abnormal heart rhythms or rates, angina or chest pains and/or circulation disorders.

Talk to your doctor or pharmacist if while using Minoxidil 5% cutaneous solution you experience low blood pressure, chest pain, rapid heart beat, faintness or dizziness, sudden weight gain, swollen hands or feet or persistent redness or irritation of the scalp.

Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water. Talk to your doctor if necessary.

The treated areas must not be exposed to sun (even when cloudy) or ultraviolet lamps (UVA). It is important to use specific protection on the treated area.

Warning Flammable Liquid and Vapour. Keep away from heat / sparks / open flames / hot surfaces – No smoking. Avoid exposure of the container and contents to naked flames during use, storage and disposal. Keep container tightly closed. Store in a well ventilated place.

Other medicines and Minoxidil 5% cutaneous solution
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Particularly those prescribed by a doctor, including:
- Betamethasone dipropionate (a corticosteroid used to treat skin disorders).
- Tretinoin (used to treat acne).
- Anthralin (used to treat psoriasis).
- Guanethidine (used to treat high blood pressure).

Minoxidil 5% cutaneous solution should not be used with any other medicines that are applied to the scalp.

Pregnancy and breast-feeding
Minoxidil 5% cutaneous solution is for men and should not be used by women. It should not be used if you are pregnant or breast-feeding.

Driving and using machines
Minoxidil 5% cutaneous solution may cause dizziness or low blood pressure. If you experience these side effects do not drive or operate machinery.

Minoxidil 5% cutaneous solution contains propylene glycol
This medicine contains 520 mg propylene glycol in each 1 ml of cutaneous solution. This may cause skin irritation.

Minoxidil 5% cutaneous solution contains ethanol
This medicine contains 243 mg alcohol (ethanol) in each ml of cutaneous solution. It may cause a burning sensation on damaged skin.

3. How to use Minoxidil 5% cutaneous solution

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the suitable dose and length of treatment with Minoxidil 5% cutaneous solution.

Minoxidil 5% cutaneous solution is for cutaneous use only. Do not ingest. It should only be applied directly to the scalp area.

Do not apply to areas of the body other than the normal healthy scalp. It should not be used on inflamed, infected, irritated or painful scalp skin.

Daily dose for adult men aged 18–65 years
The recommended daily dose is 1 ml of solution twice daily (10 sprays from the dosage pump is equivalent to 1 ml of solution).

You must respect the recommended daily dose regardless of the extent of your hair loss.

Sons

- Wash hands thoroughly with water before application.
- The hair and scalp must be completely dry when applying the solution.
- Apply a 1 ml dose of solution (10 sprays from the dosage pump) to the total affected area of the scalp starting in the centre of the area being treated.
- The solution should be massaged lightly into the scalp using your fingertips.
- After using Minoxidil 5% cutaneous solution, wash hands thoroughly with plenty of water.

If the solution is accidentally applied to an area of the body other than the scalp, rinse thoroughly with plenty of water to avoid any unwanted hair growth.

Continued use of Minoxidil 5% cutaneous solution
You may need to use this medicine twice daily for at least 2 months before you see new hair growth, this is because hair growth is a slow process.

Hair growth may be soft and downy at the start but should eventually become the same as normal hair.

When you stop using this medicine, the hair that has regrown may disappear after 3-4 months and the balding/hair loss process will continue. Continued use is necessary to increase and maintain hair re-growth, or hair loss will begin again.

If you have no improvement in your hair growth after one year of use, you should discontinue treatment.

If at any time during your treatment you are concerned you should talk to your doctor or pharmacist.

Use in women
Minoxidil 5% cutaneous solution should not be used by women.

Use in children and adolescents
Minoxidil 5% cutaneous solution should not be used in patients under 18 years.

Use in patients aged over 65 years
Minoxidil 5% cutaneous solution should not be used in patients aged over 65 years.

If you use more Minoxidil 5% cutaneous solution than you should
If you have used more Minoxidil 5% cutaneous solution than you should, tell your doctor or pharmacist immediately.

Accidental or voluntary overdose after application of minoxidil can cause an increase in the intensity of side effects affecting the skin, especially itching (pruritus), dryness, skin irritation and eczema (acute or chronic inflammatory skin disorder).

Accidental ingestion may cause serious cardiac events. The signs and symptoms of accidental or voluntary ingestion of minoxidil can include low blood pressure (hypotension), fast heartbeat (tachycardia), swelling/excessive fluid retention (oedemas) and heart failure (congestive heart disease).

If you forget to use Minoxidil 5% cutaneous solution
- In the initial treatment period: Apply the forgotten dose as soon as possible and then follow the guideline recommended by your doctor. Do not use a double dose to make up for a forgotten dose.
- In the maintenance period: Carry on as normal as if you had not missed the dose.

If you stop treatment with Minoxidil 5% cutaneous solution
If you stop treatment you may return to the initial state of hair loss before starting treatment within 3–4 months.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor right away if you notice any of the following symptoms – you may need urgent medical treatment.
- Swelling of the face, lips or throat which makes it difficult to swallow or breathe. This could be a sign of a severe allergic reaction (frequency not known, cannot be estimated from the available data).
- Swollen hands or feet (common).
- Persistent redness, rash or irritation of the scalp (not known).
- Faintness or dizziness (uncommon).
- Rapid or irregular heartbeat (rare).
- Chest pain (rare).
- Low blood pressure (not known).
- Sudden unexplained weight gain (common).

Other side effects which may occur:

Very common (may affect more than 1 in 10 people):
- Headache.

Common (may affect up to 1 in 10 people):
- Itching of the skin or rash.
- Excessive hair growth.
- Shortness of breath or difficulty breathing.

Uncommon (may affect up to 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.
- 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 two 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. This may be due to propylene glycol.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minoxidil 5% cutaneous solution

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 label. The expiry date refers to the last day of that month.

Warning Flammable Liquid and Vapour. Keep away from heat / sparks / open flames / hot surfaces – No smoking. Avoid exposure of the container and contents to naked flames during use, storage and disposal. Keep container tightly closed. Store in a well ventilated place.

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.

6. Contents of the pack and other information

What Minoxidil 5% cutaneous solution contains
- The active substance is minoxidil. Each mililitre (ml) of solution contains 50 mg of minoxidil. 1 ml is equivalent to 10 sprays.
- The other ingredients are ethanol 96%, propylene glycol and purified water.

What Minoxidil 5% cutaneous solution looks like and contents of the pack
Minoxidil 5% cutaneous solution is transparent, colourless to slightly yellowish, with an alcohol aroma. It is presented in formats of 60 ml, 120 ml (2 bottles of 60 ml) and 180 ml (3 bottles of 60 ml) with a dosage pump. Not all pack sizes may be marketed.

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This leaflet was last revised in March 2023

Package leaflet: Information for the user
Finasteride 1 mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 4.

What is this leaflet

1. What Finasteride is and what it is used for

- Finasteride 1 mg film-coated tablets contain a medicine called finasteride.

- Finasteride is used for the treatment of male pattern hair loss (also known as androgenetic alopecia). If after reading this leaflet, you have any questions about male pattern hair loss, ask your doctor.

- 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.

- In the scalp, finasteride specifically lowers the levels of DHT by blocking an enzyme (Type II 5-alpha reductase) that converts testosterone to DHT. Only men with mild to moderate, but not complete hair loss, can expect to benefit from the use of Finasteride. Finasteride increases hair growth on the scalp and prevents further hair loss in men.

2. What you need to know before you take Finasteride

Do not take Finasteride:
- If you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- If you are a woman (because this medicine is for men, see Pregnancy). It has been shown in clinical trials that finasteride does not work in women with hair loss.
- If you are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

Warnings and precautions
Talk to your doctor or pharmacist before taking Finasteride.

- 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.
- Finasteride may affect male fertility (see section 4: Possible side effects). Patients who are planning to father a child should consider stopping treatment.
- You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.
- Tell your doctor or pharmacist about any medical problems you have or have had, and about any allergies.

Mood alterations and depression
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.

Other medicines and Finasteride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Finasteride if you are already taking finasteride or dustasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

Finasteride with food and drink and alcohol
Finasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility
- **Women must not use Finasteride due to the risk in pregnancy.**
- **Do not touch crushed or broken tablets of Finasteride if you are a woman who is pregnant or planning to become pregnant.**
- If the active ingredient in Finasteride is absorbed after oral use or through the skin by a woman who is pregnant with a male baby, this may cause the male baby to be born with abnormalities of the sex organs.
- If a woman who is pregnant comes into contact with the active ingredient in Finasteride, a doctor should be consulted.
- Finasteride tablets are coated and will prevent contact with the active ingredient during normal use.

If your sexual partner is or may be pregnant, you must avoid exposing her to your semen (e.g. by using a condom).

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Sons

Driving and using machines
Finasteride is not expected to or known to affect your ability to drive or operate machinery.

Finasteride contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

Using other medicine for male pattern hair loss with Finasteride
No information is available about the use of finasteride with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

3. How to take Finasteride

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

- The usual dose is one tablet each day.
- The tablets can be taken with or without food.
- Finasteride will not work faster or better if you take it more than once a day.

Your doctor will help you to determine if Finasteride is working for you. It is important to take Finasteride for as long as your doctor prescribes it. Finasteride can only work over the long term if you continue taking it.

If you take more Finasteride than you should
If you take too many tablets by mistake, talk to your doctor promptly.

If you forget to take Finasteride
Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet as directed.

If you stop taking Finasteride
It may take 3 to 6 months for the full effect to develop. It is important to keep taking Finasteride as long as your doctor tells you.

If you stop taking Finasteride, you are likely to lose the hair you have gained within 9 to 12 months.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the side effects are temporary with continued treatment or disappeared when treatment is stopped.

Stop taking Finasteride and talk to your doctor if you experience:
- symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking Finasteride and talk to your doctor immediately
- depression (feeling of severe sadness and unworthiness)
- you should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Uncommon (may affect up to 1 in 100 people):
- less desire to have sex
- difficulty having an erection
- problems with ejaculation such as a decrease in the amount of semen released.

Frequency not known (frequency cannot be estimated from the available data):
- 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 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.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasteride

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.

6. Contents of the pack and other information

What Finasteride contains
- The active substance is finasteride. Each film-coated tablet contains 1 mg finasteride.
- The other ingredients are:

Tablet core:
lactose monohydrate, maize starch pregelatinised, docusate sodium, iron oxide yellow (E172), sodium starch glycolate (type A), cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, water purified.

Tablet coat:
hydroxypropyl cellulose, hypromellose, talc, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

What Finasteride looks like and contents of the pack

Finasteride tablets are round biconvex red film-coated tablets with a 6.5 mm nominal diameter.

Finasteride film-coated tablets are available in white PVC/PE/PVDC/ Aluminium and/or Aluminium/ Aluminium blisters. The blisters are packed in cardboard boxes containing 14, 20, 28, 30, 50, 60 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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