

Package leaflet: Information for the user

Minoxidil for men 5% w/v 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 cutaneous solution is and what it is used for
2. What you need to know before you use Minoxidil cutaneous solution
3. How to use Minoxidil cutaneous solution
4. Possible side effects
5. How to store Minoxidil cutaneous solution
6. Contents of the pack and other information

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

Minoxidil 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 cutaneous solution

Do not use Minoxidil 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

Your doctor must carry out a full medical examination before you start treatment with Minoxidil cutaneous solution. Talk to your doctor or pharmacist before using Minoxidil 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.

Cases of excessive hair growth on the body of infants have been reported following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hair growth returned to normal within months when infants were no longer exposed to minoxidil. Care should be taken to ensure that children do not come into contact with areas of your body where you have applied minoxidil topically. Consult a doctor if you notice excessive hair growth on the body of your child during the period you are using topical minoxidil products.

Talk to your doctor or pharmacist if while using Minoxidil 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 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 cutaneous solution should not be used with any other medicines that are applied to the scalp.

Pregnancy, breast-feeding and fertility

Minoxidil 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 cutaneous solution may cause dizziness or low blood pressure. If you experience these side effects do not drive or operate machinery.

Minoxidil cutaneous solution contains ethanol

This medicine contains 455.5 mg alcohol (ethanol) in each ml of cutaneous solution. It may cause a burning sensation on damaged skin.

3. How to use Minoxidil 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 cutaneous solution.

Minoxidil 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.

- Before use, unscrew the bottle cap and replace it with the dosage pump. Screw the dosage pump into place securely.
- 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 cutaneous solution, wash hands thoroughly with plenty of water.



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

Continued use of Minoxidil 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 4 months 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 cutaneous solution should not be used by women.

Use in children and adolescents

Minoxidil cutaneous solution should not be used in patients aged under 18 years.

Use in patients aged over 65 years

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

If you use more Minoxidil cutaneous solution than you should

If you have used more Minoxidil 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).

Accident ingestion may cause serious cardiac adverse 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 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. Apply the following dose as usual and continue the treatment.

If you stop treatment with Minoxidil 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 heart beat (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.
- Depressed mood

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minoxidil cutaneous solution

Keep this medicine out of 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.

Once opened use within 30 days.

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 cutaneous solution contains

- The active substance is minoxidil. Each millilitre (ml) of solution contains 50 mg of minoxidil. 1 ml is equivalent to 10 sprays.
- The other ingredients are ethanol 96 %, glycerol, 2-butenedioic acid, polymer with methoxyethene, monobutyl ester and purified water.

What Minoxidil cutaneous solution looks like and contents of the pack

Minoxidil 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), 180 ml (3 bottles of 60 ml) and 240 ml (4 bottles of 60 ml) with a dosage pump.

Not all pack sizes may be marketed.

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