

Minoxidil 5 Scalp solution

Active ingredient: minoxidil 5%

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. You must use this medicine according to the instructions in the dosage section in this leaflet. Consult your pharmacist if you need further information.

Minoxidil 5 is intended for men aged 18-65 years in cases of hereditary hair loss only.

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

1. What is this medicine intended for?

Minoxidil 5 is intended for scalp hair growth in healthy men aged 18-65 years, in cases of hereditary hair loss only. Consult your doctor to ensure that your type of hair loss is suitable for treatment with this medicine.

Therapeutic group: vasodilators in local administration for treatment of hair loss.

The medicine contains minoxidil, which is considered a substance that works by helping the blood flow to the scalp hair follicles.

- The medicine is intended for men aged 18-65 years.
- Minoxidil 5 works best in men with hair loss or thinning at the top of the scalp.
- Those who are younger, have been losing hair for a short period of time or have a small area of baldness are likely to experience the best results.
- You are unlikely to benefit from Minoxidil 5 if you have been bald for many years or have a large area of hair loss.

Hereditary hair loss is recognisable according to the following signs:

- The pattern of hair loss (see diagrams).
- It starts gradually and progresses.
- You have a family history of hair loss.
- No other symptoms are present with your hair loss.



What you need to know before you use this medicine

This medicine is suitable for most people, but certain people must not use it. If you are in any doubt, talk to your doctor or pharmacist.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient, ethanol, propylene glycol or to any of the other ingredients in this medicine (see section 6).
- you are a woman.
- **you are under the age of 18 or over the age of 65.**
- you are not sure if your hair loss is hereditary.
- you have hair loss caused by drug treatment.
- you have total baldness or complete loss of all body hair.
- the cause of your hair loss is unknown, or it is sudden and unexpected.
- you have **high blood pressure**, even if it is not being treated.
- you have **any problem that affects your scalp**, including sunburn and psoriasis.
- you **shave your scalp**.
- you are using **creams, ointments or lotions** used to treat scalp conditions, e.g.
 - Dithranol - used to treat psoriasis.
 - Tretinoin - used to treat acne or other skin disorders.
 - Corticosteroids - a type of anti-inflammatory.
 - Petrolatum - a common ingredient in hair wax or gel.
- you have any kind of **dressings or bandage** on your scalp.
- you are unsure of whether the skin on your scalp is **normal and healthy**.

If any of these bullet points apply to you now or in the past, **get advice from a doctor or pharmacist before using Minoxidil 5.**

Special warnings about using this medicine

Consult your doctor or pharmacist in the following cases

- you are unsure of whether the skin on 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.

Additional warnings

- If minoxidil passes into the blood stream, it can cause some side effects related to low blood pressure such as chest pain, rapid heart beat, faintness, dizziness, swollen hands and feet, persistent redness or irritation of the scalp. If you experience any of the side effects in this list, **stop using the medicine and contact your doctor**. When Minoxidil 5 is used as recommended, it is extremely unlikely that these effects will occur. However, there is a chance the medicine could get into the blood stream if it is over used or if there is a scalp condition such as psoriasis. Therefore it is very important that you use the medicine as recommended and follow the instructions very carefully. See section 3.
- Warning: Flammable liquid. Keep away from heat/sparks/open flame/hot surfaces. No smoking in its vicinity. 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. Keep in a cool place.
- 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 the areas thoroughly with plenty of water.
- Do not apply to areas of the body other than the scalp.
- Accidental ingestion may cause serious cardiac side effects. Therefore this product has to be kept out of the reach of children.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- certain blood pressure medicines (vasodilators - widen blood vessels) e.g. hydralazine. There is a risk that minoxidil, the active ingredient in Minoxidil 5 will interact with these medicines and increase their effect.

If you are not sure about the medicine you are taking or using, show the bottle or pack to your pharmacist.

If any of the items above applies to you now or in the past, **consult with your doctor or pharmacist**.

Pregnancy and breast-feeding

This product is intended for men and is not intended for use by women. It should not be used if you are pregnant or breast-feeding.

Driving and using machines

Minoxidil 5 may cause dizziness or low blood pressure. If you experience these side effects do not drive or operate machinery.

Important information about some of this medicine's ingredients

- The medicine contains propylene glycol which may cause skin irritation.
- Minoxidil 5 contains 244 mg alcohol (ethanol) in every 1 ml of solution, equal to 24.4% w/v. May cause a burning sensation and irritation if it comes into contact with damaged skin or gets into your eye. If Minoxidil 5 gets in your eye, mouth or on damaged skin or a cut, wash the area well with lots of cool tap water.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The product is for topical and external use only, and should be applied directly to the scalp.

The dosage is usually:

The maximum amount for treatment is 2 ml a day: 1 ml in the morning and 1 ml in the evening (1 ml = 7 sprays). Leave at least 12 hours between each use.

Frequent use and/or use of a larger amount will not increase hair growth, but may cause more side effects. **Therefore make sure to measure the dose by the recommended number of sprays.**

Do not exceed the recommended dose.

On a completely dry scalp and hair, use a total of 1 ml of the product on all bald areas. If possible, start at the centre of the bald area and, with a clean finger spread the product. After application, wash your hands and any area that came into contact with the solution well.

Avoid allowing Minoxidil 5 to drop onto the face or on areas of skin outside the bald areas. If it accidentally spills on an area that is not the scalp, rinse well with plenty of water. Avoid breathing in the spray whilst applying to the scalp.

After using Minoxidil 5: Avoid washing your hair for about two hours. Do not use a hair dryer to dry the solution on your hair faster. Do not rest your head on a pillow for at least one hour after applying it on your scalp. Avoid from exposing your hair to the sun.

Instructions for use:

- Remove the clear plastic cap.
- Open the extended tip applicator.

- Hold the bottle vertically, spray the solution on the affected area and use your fingertips to spread it over the desired area. The total amount of solution used (on all bald areas together) is a maximum of 7 sprays.
- Wipe the spray-tip applicator after use, fold it down and close the clear plastic cap.

How can you contribute to the success of the treatment?

Only apply the product when the scalp and hair are completely dry. Adhere to the treatment according to the instructions.

Users who are younger and/or who have been losing hair for a short period of time and/or have a small area of baldness may experience better results. If the balding process started years ago and/or the bald area is extensive, the likelihood of success with the treatment is low.

Continued use of Minoxidil 5

- You may need to use this medicine twice daily for at least two 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.
- Once the hair has begun to re-grow, you need to continue using this medicine twice a day for the growth to continue. In clinical trials with minoxidil, 3 out of every 5 men reported hair re-growth after 48 weeks of continual use of this product.
- When you stop using the medicine, the hair that has re-grown may disappear after 3-4 months and the hair loss and balding process will continue.
- If you experience 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 consult your doctor or pharmacist.

Do not light a cigarette or expose yourself to a flame until the product has dried completely.

If you forget to apply a dose of the solution

If you miss one or two applications, just carry on as normal as if you had not missed the dose - **do not use twice as much or twice as often**.

If you have taken an overdose, or if a child or adult has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you (with the bottle of Minoxidil 5 if possible, because the doctor may want to get an indication of how much of the substance was swallowed).

Swallowing the product may lead to serious problems with heart function. **Note:** Do not swallow. This medicine is intended for external use on the scalp only. Avoid breathing spray mist.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Minoxidil 5 may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

If one or more of the following effects develops, stop using the medicine and contact your doctor immediately:

- Chest pain.
- Swelling of the face, lips, mouth, tongue or throat which may cause

difficulty in swallowing or breathing.

If one or more of the following effects develops, stop use and contact your doctor:

- Allergic reactions including swollen face, skin redness or itching or throat tightness.
- Low blood pressure.
- Fast heart beat or an increased awareness of the heart beat (palpitations).
- Feeling faint or dizzy.
- Swollen hands or feet, shortness of breath.
- Sudden unexplained weight gain.
- Persistent local redness or rash.

Change in hair texture (rare - may affect up to 1 in 1,000 users) or change in hair colour (frequency unknown) may occur. If this happens, **you should stop using Minoxidil 5.**

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.**

Additional side effects

Very common side effects (may affect more than one in 10 users):

- Headache

Common side effects (may affect up to 1 in 10 users):

- Itching or inflammation of the skin (dermatitis)
- Unwanted growth of non scalp hair (including facial hair growth in women).

Always wash your hands thoroughly after application and if you accidentally apply the solution to parts of your body other than the scalp, rinse thoroughly with plenty of water.

Uncommon side effects (may affect up to 1 in 100 users):

- Nausea

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- Depressed mood
- Eye irritation
- Vomiting
- Scalp irritation such as local redness, dryness, flaky skin. This may be due to propylene glycol in the product. This is usually only a temporary effect, but if it is persistent, **you should stop using this product**.
- Acne like rash, itchy rash, blistering, bleeding or ulceration.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il> You may also report to e-mail: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. Date) which is

stated on the package/label. The expiry date refers to the last day of that month.

- **Storage conditions:** Store in a cool place, below 25°C.
- After first opening the bottle, the medicine may be used for up to six months and no later than the expiry date.
- The product is flammable. Keep away from flame or heat source. Do not light a cigarette or expose yourself to a flame until the product has dried completely.

6. Additional information

In addition to the active ingredient, this medicine also contains: Propylene glycol, alcohol, purified water, dexpantenol.

What the medicine looks like and contents of the pack:

The pack contains 1 or 2 spray bottles that contain 80 ml of solution each.

Not all pack sizes may be marketed.

Manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in July 2022 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 109.97.29349.00