

**PATIENT PACKAGE INSERT IN  
ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

## **MINOXI 5 SCALP SOLUTION**

**Composition:** The active ingredient: Minoxidil 5%  
Inactive and allergenic ingredients in the preparation - see section 6.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

**Minoxil 5 is intended for men aged 18-65 years in cases of balding of the hereditary type only.**

You must use it in the correct manner. Consult the pharmacist if you need further information.

Frequent use and/or use of a larger amount will not increase hair growth, may even cause more side effects and can even cause side effects related to decreased blood pressure, such as: chest pain, dizziness, fainting, rapid heartbeat, swelling of the limbs. If one of these effects occurs, stop use and refer to a doctor immediately.

Adhere to the treatment as per the instructions. Do not use on other areas except for the scalp.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Minoxil 5 is intended for scalp hair growth among healthy men aged 18-65 in cases of hereditary-type balding only. Consult the attending doctor to confirm that your type of hair loss is suitable for treatment with this preparation.

**Therapeutic group:** Vasodilators, for local use, to treat hair loss.

### **2. BEFORE USING THE MEDICINE**

**X Do not use the medicine if:**

- You are a woman.
- You are younger than the age of 18 years or older than 65 years.
- You are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine (see section 6).
- The hair loss you are suffering from is not of hereditary origin.
- The reason for the hair loss is unknown or if the hair loss is sudden and unexpected.
- The hair loss is caused by pharmaceutical treatment you are receiving.
- You are completely bald or you have lost all of your body hair.
- You suffer from hypertension, even if not treated.
- You suffer from any condition that affects the scalp (such as: sunburn, psoriasis, etc.).
- You shave your scalp.
- You use various creams, ointments or lotions intended for treatment of scalp problems, such as: dithranol (for treatment of psoriasis), tretinoin (to treat acne or additional skin problems), corticosteroids (anti-inflammatory agents, such as: hydrocortisone, betamethasone), paraffin (petrolatum) - a common ingredient in hair creams.
- You have any type of dressing on the scalp.
- Your scalp is damaged or unhealthy.

### **Special warnings regarding use of the medicine:**

- Consult with your doctor if you are suffering, or have suffered, from impaired function of the heart (including arrhythmias, angina pectoris or chest pain and/or blood circulation problems and/or hypertension), the kidney, the blood system (such as coagulation, etc.).
- Make sure, before use of the medicine, that the scalp is healthy and not damaged.
- Only use this preparation on the scalp.
- If Minoxil passes into the blood stream, it can cause side effects that arise from low blood pressure, such as: chest pain, rapid heartbeat, fainting, dizziness, swelling of the hands and feet, persistent redness or irritation of the scalp. If you experience any of the side effects listed here, stop using the medicine and refer to a doctor immediately. When using the preparation as instructed, it is highly unlikely that these side effects will occur. The risk increases if the preparation was used on damaged skin (such as psoriasis) or following overdose.
- If you are sensitive to any food or medicine, inform the doctor before use of the medicine.
- Be sure to wash your hands immediately after using the preparation. Avoid contact with the eyes, mouth, damaged skin and sensitive areas. If such contact is made, rinse with a lot of water.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist regarding medicines from the following groups:

- Treatment of hypertension (vasodilators, such as hyalazine) - for fear of increase in their activity.
- Local treatment of the scalp.

### **Pregnancy and breastfeeding:**

The medicine is intended for men only.

### **Smoking:**

The preparation is flammable; therefore, do not smoke near it. Do not light a cigarette or be exposed to fire until the preparation has completely dried.

### **Important information regarding some of the ingredients in this medicine:**

Propylene glycol, which is included in the solution, may cause irritation of the scalp.

The preparation also contains alcohol (ethanol), which upon contact with the eyes, may cause burning and irritation. If the preparation gets into the eyes, mouth or comes into contact with damaged skin, wash the area under cold running tap water.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Check with the doctor or pharmacist if you are uncertain. Only use the preparation locally and externally, directly on the scalp.

The usual dosage is generally according to the following instructions:

The maximal amount for treatment is 2 ml per day: 1 ml in the morning and 1 ml in the evening (1 ml = 7 sprays). Allow 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, **be sure to measure the dose by the recommended number of sprays.**

The hair growth process, like the balding and hair loss process, is prolonged; therefore, use the preparation for at least two months in order to assess hair regrowth. If you do not see improvement after a few months, refer to the attending doctor.

### **Do not exceed the recommended dose.**

Use the preparation on completely dry hair and scalp, at a total amount of 1 ml for the entire balding areas. If possible, begin at the center of the balding area and spread the solution with a clean finger. After application, thoroughly wash your hands and any area that has come into contact with the solution. Avoid dripping Minoxil 5 on the face or on skin areas outside of the balding area. If some of it was accidentally spilled onto an area other than the scalp, wash it well with a lot of water. Make sure not to inhale the spray when spraying on the scalp. After using Minoxil 5: avoid washing the head for approximately two hours. Do not use a hair dryer to hasten hair drying from the solution. Do not place your head on a pillow for at least one hour after application of the scalp. Avoid exposure of the hair to the sun.

How to use:

- a. Remove the transparent plastic cover.
- b. Hold the bottle vertically, spray the solution onto the treated area and spread onto the entire desired area, using the tips of the fingers. The total quantity of solution to be used (on all the balding areas together) is no more than 7 sprays.

The initial hair growth may look soft and downy, but the hair will eventually grow as normal hair.

Continue the treatment even after the hair starts to grow again. Continue using twice a day, as per the instructions.

If you do not see an improvement in hair growth after one year of use, stop the treatment.

**If you forget to apply the medicine** at the required time, continue the treatment as per the instructions. Wait at least 12 hours between each use. Do not apply a double dose.

### **How can you contribute to the success of the treatment?**

Only apply the preparation when the scalp and hair are completely dry. Adhere to the treatment as per the instructions. Cessation of treatment will most likely lead to loss of the hair that has grown and renewal of hair loss within 3-4 months. Young users and/or users whose balding started a short time ago and/or their area of balding is not extensive, may benefit from better results. If the balding process began many years ago and/or the balding area is extensive, the chances of treatment success are low.

### **Tests and follow-up**

During the treatment period with this medicine, blood, urine, kidney, heart and respiratory system function tests should be performed. Be alert for changes in your general feeling and health condition. If you are sensitive to any food or medicine, inform the doctor before using the medicine. You should be weighed twice a week; in case of sudden weight gain, refer to the doctor immediately. Patients treated with this medicine who have heart diseases and/or hypertension must be under medical supervision throughout the entire treatment period. Do not use on an inflamed, irritated and/or red scalp or during treatment with another preparation.

**Attention:** Do not swallow; this medicine is intended for external use on the scalp only. Avoid inhalation of the spray. If you took an overdose or if a child or adult accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Swallowing the preparation may cause severe heart function problems. Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

### **4. SIDE EFFECTS**

As with any medicine, use of Minoxil 5 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop use of the preparation and refer to a doctor or a medical center immediately if one or more of the following effects develop:**

- Chest pain.
- Swelling of the face, lips, mouth, tongue or throat, which cause difficulty in swallowing and breathing.

**Discontinue use and consult with the doctor if one or more of the following effects develop:**

- Allergic reactions, which include redness or irritation of the skin or pressure in the throat, low blood pressure, fast heartbeat, palpitations (a feeling of rapid and strong heartbeats), fainting and dizziness, swelling of the limbs, shortness of breath, sudden and unexplained weight gain, persistent redness or local itching.

### **Additional side effects**

#### **Very common side effects:**

- Headache.

#### **Common side effects:**

- Itching, skin inflammation (dermatitis), increased hair growth.

#### **Uncommon side effects:**

- Eye irritation.
- Nausea, vomiting.
- Irritation of the scalp, including local redness, dryness, scaly skin. These effects can be caused by the propylene glycol component found in the product. These effects are usually temporary. If they do not pass, stop using the preparation.
- Acne-like rash, itchy rash, blisters, bleeding or ulcer.
- Unwanted hair growth outside of the scalp (including reports of hair growth in facial areas in women). Be sure to wash the hands after application. If you put the solution on another area of the body aside from the scalp, rinse immediately with a lot of water.
- Temporary hair loss may occur during the first 2-6 weeks of treatment. This is probably because of the change in the hair growth cycle. This hair loss should stop within two weeks. If the hair loss continues for more than two weeks, stop using Minoxil 5 and consult the doctor.
- A change in the color and texture of the hair. If such a change happens, stop using the preparation.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:  
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.
- Store in a cool place, at a temperature below 25°C.
- The product is flammable. Keep away from fire and/or heat sources. Do not light a cigarette or be exposed to fire until the preparation has completely dried.

### **6. FURTHER INFORMATION**

- In addition to the active ingredient, the medicine also contains:  
Propylene glycol, alcohol 95%, purified water, dextranthenol.
- **What does the medicine look like and what are the contents of the package?**  
The package contains a spray bottle comprised of 80 ml solution.
- Manufacturer and license holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health in July 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 109.97.29349.00.