

The medicine is dispensed without a doctor's prescription

# Noxidil 5%

## Solution for topical treatment of the scalp

### Composition:

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

**Read the 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.

**This preparation is intended for men aged 18-65 years, in cases of balding of the hereditary type only.** You must use properly. Consult the pharmacist if you need further information.

Application of the preparation on the scalp's skin stops hair loss and results in hair growth in cases of baldness in some users of the preparation. Studies carried out to date indicate that 3 out of 5 men who used minoxidil for 48 weeks, reported hair growth.

Users who are young and/or whose balding process began a short time ago and/or whose balding area is not extensive, may obtain better results.

If the balding process began many years ago and/or the balding area is extensive, the prospects of successful treatment are low.

The hair growth process, like the balding and hair loss process, is prolonged; therefore, the preparation should be used 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. Full evaluation of the effect of the preparation will only be possible after one year of treatment; therefore, if you do not see improved hair growth after one year of use, stop the treatment.

The maximal daily dosage is 2 ml: 1 ml in the morning and 1 ml in the evening (1 ml = 7 sprays).

Frequent use and/or use of a larger amount will not increase hair growth and may even cause more side effects and even cause side effects associated with a decrease in blood pressure, such as: chest pain, dizziness, fainting, rapid heart rate, swelling of the limbs. If any of these effects occur, stop use and refer to the doctor immediately.

Adhere to the treatment according to the instructions. Do not use on areas other than the scalp.

Use of the preparation is long-term.

Interruption of treatment may cause renewed hair loss within 3-4 months.

## 1. WHAT IS THIS MEDICINE INTENDED FOR?

The preparation is intended for scalp hair regrowth among healthy men aged 18-65 years 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 topical application, for the treatment of hair loss.

## 2. BEFORE USING THE MEDICINE

### ❗ 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 minoxidil or to any of the other ingredients contained in the medicine (see section 6).
- the hair loss you are suffering from is not of hereditary origin (e.g., sudden and unexpected hair loss, hair loss as a result of medicinal treatment).
- 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's skin (e.g., 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 - used to treat acne, corticosteroids - anti-inflammatory agents, e.g., hydrocortisone, betamethasone, paraffin - a common ingredient in hair creams.
- you have any type of dressing on the scalp.

### Special warnings regarding use of the medicine

- If you suffer, or have suffered, from impaired function of the heart (including arrhythmias, angina pectoris or chest pains and/or blood circulation problems and/or hypertension), the kidney, the blood system (e.g., coagulation, etc.), inform the doctor before use of the medicine.
- Make sure, before use of the medicine, that the skin of the scalp is healthy and not damaged.
- If you are sensitive to any type of food or medicine, inform the doctor before use of the medicine.
- **Warning! Flammable, keep away from fire. Do not light a cigarette or be exposed to an open flame until the product has completely dried.**

### ❗ Drug interactions

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.** Especially inform the doctor or pharmacist about medicines from the following groups:

- For treatment of hypertension (e.g., hydralazine) - for fear of increase in their activity.
- For topical treatment of the scalp.

### ❗ Pregnancy and breastfeeding

The medicine is intended for men only.

### ❗ Smoking

The preparation is inflammable; therefore, do not smoke near it.

### ❗ Important information regarding some of the medicine's ingredients

The ingredient propylene glycol included in the solution may cause irritation of the scalp's skin.

The preparation also contains alcohol, which, upon contact with the eyes, may cause burning. If the preparation comes into contact with the eyes, mouth or damaged skin, rinse the area under running tap water.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

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 an interval of at least 12 hours between each use. More 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.** **Do not exceed the recommended dose.** Use the preparation on 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, wash your hands well. Avoid dripping the preparation on the face or on skin areas outside of the balding area. If some of it accidentally spilled onto an area other than the scalp, wash it well. After using the preparation: avoid washing the head for 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 on the scalp. Avoid exposure of the hair to the sun.

Use the atomizer (included in the package), for treatment of balding and balding areas partially covered with hair:

- a. Remove the plastic cover and put the atomizer on in its place.
- b. Hold the bottle vertically and spray the solution onto the treated area.

The total quantity of solution to be used (on all the balding areas together) should be no more than 7 sprays.

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

**If you forget to apply the medicine** at the required time, apply a dose as soon as you remember, unless you remembered almost at the time for the next treatment. 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 according to the instructions. Interruption of treatment will most likely lead to loss of the hair that has grown and renewal of hair loss within 3-4 months.

### Tests and follow-up

During the treatment period with this medicine, you should perform blood and urine tests, kidney, heart and respiratory system function tests. 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 inhaling the spray.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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



## 4. SIDE EFFECTS

As with any medicine, use of the preparation 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.

**Discontinue use, and refer to the doctor if one or more of the following effects develop:**

- Irritation/redness, persistent and/or severe local inflammation or rash, acne, edema in various parts of the body, swelling of the face, numbness of the legs, hands or face, swelling of the limbs, chest pain, shortness of breath or difficulty breathing, dizziness, fainting, accelerated heartbeats, low blood pressure, headache, sudden and unexplained weight gain, low white blood cell count (leukopenia).
- Hair loss that may appear at the beginning of treatment (the first 2-6 weeks of treatment) and persists for more than two weeks.
- If certain effects do not pass, such as: local redness in the treated area, itching, dryness of the scalp, dandruff (these effects are mostly transient).
- Change in hair color or texture.

### Additional side effects which occur frequently:

- Hair growth on other body parts, including the face.
- Itching, including an itchy rash in the area of application and/or itching in other parts of the body (including the eyes).

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

### Reporting side effects:

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=AdverseEffectMedic@moh.gov.il>

In addition, you can report to Perrigo via the following address:

[www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and the bottle. The expiry date refers to the last day of that month.
- Store below 25°C.
- The product is inflammable. Keep away from fire and/or heat sources.
- After first opening use within a month, but not later than the expiry date.

## 6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Propylene glycol, alcohol, purified water.
- What does the medicine look like and what are the contents of the pack? Each bottle contains 60 ml of solution. The package also contains atomizer.
- This leaflet was checked and approved by the Ministry of Health in: April 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 144-70-33300.
- Registration holder, manufacturer and address: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Marketed by: SuperPharm (Israel) Ltd., P.O.B. 2171, Herzliya 4672516.