

## **PACKAGE LEAFLET: Information for the user**

### **NEW HAIR**

Solution for topical use – 5%

(Minoxidil)

**Read this leaflet carefully before you start using this medicine.**

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet**

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#### **1. WHAT NEW HAIR 5% SOLUTION FOR TOPICAL USE IS AND WHAT IT IS USED FOR**

New Hair 5% solution for topical use contains the active substance minoxidil at a concentration of 50 mg/ml. It is a medicine in liquid form which is applied directly on the scalp.

It is used as a treatment for hair loss and not as a cure. Minoxidil is a peripheral vasodilator, whose exact mechanism of restoring hair growth is not known.

New Hair 5% solution for topical use is indicated for use in men aged 18 to 65 years, with gradual weakening or loss of hair on the top of the head. Weakening or loss of hair is a slow process, which may become evident only after several years of gradual loss.

See your doctor if you notice no improvement or if you notice worsening of symptoms after 4 months.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE NEW HAIR 5% SOLUTION FOR TOPICAL USE**

**Do not use New Hair 5% solution for topical use:**

- if you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6).

New Hair 5% solution for topical use is not indicated in cases of alopecia areata (sudden or unexplained hair loss) or cicatricial alopecia (associated with scarring skin, such as a burn or ulcer). In addition, New Hair 5% solution for topical use should not be used if hair loss is associated with serious medical conditions, such as thyroid malfunction, lupus, loss of sections of hair associated with inflammation of the scalp or other conditions.

### **Warnings and precautions**

Consult your doctor or pharmacist before using New Hair 5% solution for topical use.

Apply New Hair 5% solution for topical use only on normal and healthy scalp. You should not initiate the application of New Hair 5% solution for topical use if hair loss is sudden or unexplained or if hair loss follows an illness or therapy. If you have any other questions about hair loss, see your doctor before using New Hair 5% solution for topical use.

If you suffer or have suffered in the past from heart or vascular disease, including irregular heartbeat, you should consult a doctor before using New Hair 5% solution for topical use.

You should not apply New Hair 5% solution for topical use if the affected area is red and inflamed, irritated or sore, as in the case of severe sunburn or seborrheic dermatitis.

You should not apply New Hair 5% solution for topical use to other parts of the body or in conjunction with other topical medications.

If you observe unusual symptoms after applying New Hair 5% solution for topical use, discontinue the application and seek medical advice. It is especially important to discontinue the application of New Hair 5% solution for topical use in case of increased heart rate (palpitations), swelling of hands and feet, sudden weight gain without apparent cause, chest pain, weakness and/or dizziness. You should also discontinue application if the scalp is reddened or irritated.

The development of systemic effects (e.g., increased heart rate or fluid retention) is greater in patients with known or suspected coronary heart disease and in patients with predisposition to myocardial infarction. When deciding to use New Hair 5% solution for topical use, patients with this type of disease and their doctors should be aware of the risks.

New Hair 5% solution for topical use should only be applied to the scalp because in other parts of the body the absorption of minoxidil may be greater and increases the incidence of undesirable effects.

If the scalp is irritated or burned after sun exposure, New Hair 5% solution for topical use should not be applied.

Furthermore, New Hair 5% solution for topical use should not be applied to the scalp along with other topical medications.

Do not ingest this medicinal product.

Do not inhale this medicinal product.

### **Children and adolescents**

New Hair 5% solution for topical use should not be used in patients under 18 years of age.

### **Other medicines and New Hair 5% solution for topical use**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. To date, no information is available on interactions between minoxidil 5% solution and other agents. Although not clinically proven, there is a theoretical possibility that absorption of the active substance minoxidil into the body may worsen orthostatic hypotension (a drop in blood pressure felt when standing up from a lying position) in patients

who are also taking peripheral vasodilators (certain high blood pressure medicines which widen the blood vessels).

New Hair 5% solution for topical use should not be used together with other dermatological products (preparations for external use containing active substances such as corticosteroids, retinoids or dithranol) or with agents that increase absorption of the active substance through the skin (skin absorption).

### **Pregnancy and breastfeeding**

May be harmful if used when pregnant or breastfeeding.

### **Driving and using machines**

New Hair 5% solution for topical use should not affect your ability to drive vehicles or operate machinery.

### **Important information about some of the excipients of New Hair 5% solution for topical use**

This medicine contains 350 mg propylene glycol (E 1520) in each ml. It may cause skin irritation.

New Hair 5% solution for topical use contains 480 mg alcohol (ethanol 96%), which may cause burning sensation on damaged skin and irritation of the eyes. In case of accidental contact with sensitive surfaces (eyes, injured skin and mucous membranes), the affected area should be washed with plenty of cool tap water.

## **3. HOW TO USE NEW HAIR 5% SOLUTION FOR TOPICAL USE**

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.

New Hair 5% solution for topical use is intended for external use on the dry scalp. Please use this medicine only on healthy, undamaged scalp and follow the instructions for use below exactly at all times. Do not apply New Hair 5% solution for topical use to body areas other than the scalp.

**Recommended dose**

Unless otherwise prescribed by the doctor, New Hair 5% solution for topical use must be used as follows: Apply a dose of New Hair 5% solution for topical use (1 ml) twice daily (morning and evening) directly to the area of the scalp where you observe hair loss. Distribute the dose over the entire affected area, massaging it in with your fingertips.

The daily amount applied should not be exceeded, regardless of the size of the affected skin area.

**Use in children and adolescents**

New Hair 5% solution for topical use must not be used in children and adolescents below 18 years.

**Instructions for use/application**

Apply one dose (1 ml) twice a day directly onto the scalp within the area of hair loss. You should not apply higher doses than recommended. This medicine should not be applied in areas other than the scalp.

The applicator is designed to dispense one dose (1 ml) of New Hair 5% solution for topical use. Massage the applied amount over the entire area to be treated. Wash your hands after each application.

For the priming of the pump, press down on the pump 6 times. After each pumping action, spread the liquid over the affected area with your fingertips. At the same time, avoid breathing in the spray mist. Wash hands thoroughly after use.

If at the time of starting treatment with New Hair 5% solution for topical use you have very little hair and respond to the treatment, your new growing hair will initially be soft and velvety, not very visible. As the treatment continues, the new hair will acquire a colour and texture similar to other hairs. If hair loss is not very pronounced at the start of the treatment, the new hair that will grow will have a colour and texture similar to other hairs.

The onset and extent of hair growth are different in individual patients. Clinical studies have shown that the response to treatment is very variable and that results are not immediate.

Generally, hair regrowth is gradual and it is necessary to continue application twice a day for at least 4 months for it to be visible.

As New Hair 5% solution for topical use starts to act on the hair follicles, a temporary increase in hair loss may be observed about 2-6 weeks after starting treatment.

If you wash your hair before applying New Hair 5% solution for topical use you should use a mild shampoo.

While using New Hair 5% solution for topical use it is not necessary to change the standard care you usually give to your hair. However, you should apply New Hair 5% solution for topical use first, let your hair dry, and only then apply hairspray, mousse, conditioner, gel or any other product (in the case of hair dye, perm, etc.). If you plan to swim or get your hair wet, it is preferable to apply New Hair 5% solution for topical use to your dry scalp after swimming, or wait two hours after applying the product. You should leave New Hair 5% solution for topical use on the scalp for at least 2 hours.

This medicine is for topical use only.

Avoid exposure to the sun just after applying New Hair 5% solution for topical use.

### **If you use more New Hair 5% solution for topical use than you should**

Application of New Hair 5% solution for topical use at higher than the recommended dosage and to relatively large body surfaces or areas other than the scalp may possibly lead to increased absorption of minoxidil into the body. To date, there have been no known cases where the external use of minoxidil solution has resulted in symptoms of poisoning. After accidental swallowing, the concentration of the active component minoxidil in New Hair 5% solution for topical use may lead to effects on the inner organs corresponding to the effects which result when the active substance is swallowed, e.g. in a tablet. This may cause the following side effects: faster heartbeat, drop in blood pressure, fluid accumulation and subsequent sudden weight gain, dizziness. In case of accidental ingestion or if signs of overdose occur, please tell a doctor immediately, so that he/she can decide what to do next. Please keep the medicine pack ready to hand, so that the doctor can be informed about what active substance has been taken.

If you experience any side effects related to the use of New Hair 5% solution for topical use that are not listed in this leaflet, contact your doctor or pharmacist immediately.

**If you forget to use New Hair 5% solution for topical use**

Do not apply a double dose to make up for a forgotten dose; continue your treatment at the recommended dose. Making up for the missed dose will bring no benefit and might lead to undesirable effects.

**If you stop using New Hair 5% solution for topical use**

In order to maintain hair growth, the recommended dose of New Hair 5% solution for topical use must be applied continuously. 3-4 months after stopping treatment with New Hair 5% solution for topical use the growth of new hair stops and the hair loss process returns to the normal pre-treatment state.

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 side effects – 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).

**Very common (may affect more than 1 in 10 people):**

- Headache

**Common (may affect up to 1 in 10 people):**

- Depressed mood
- Dyspnoea (shortness of breath)
- Itching, hypertrichosis (abnormal hair growth), rash, acneiform rash, dermatitis, inflammatory skin disorder

- Musculoskeletal pain
- Peripheral oedema
- Pain

**Uncommon (may affect up to 1 in 100 people):**

- Skin dryness, temporary hair loss, hair texture changes, hair colour changes
- Application site irritation

**Rare (may affect up to 1 in 1,000 people):**

- Palpitations, increased heart rate, chest pain
- Erythema at the site of application

**Very rare (may affect up to 1 in 10,000 people):**

- Hypotension.

If you develop one of the side effects described above, please inform your doctor or pharmacist.  
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. HOW TO STORE NEW HAIR 5% SOLUTION FOR TOPICAL USE**

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 package.

Do not store above 25°C!

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What New Hair 5% solution for topical use contains**

**The active substance** is minoxidil.

1 ml solution contains 50 mg minoxidil.

**The excipients** are ethanol, propylene glycol (E 1520), lactic acid, and purified water.

**Content of the pack**

Carton box with 1 plastic bottle of 60 ml;

Carton box with 3 plastic bottles of 60 ml.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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**This leaflet was formulated in August 2023.**