

Package leaflet: Information for the patient

Minorga 5%, cutaneous solution

Minoxidil

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 have 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 months.

What is in this leaflet

1. What Minorga 5%, cutaneous solution is and what it is used for
2. What you need to know before you use Minorga 5%, cutaneous solution
3. How to use Minorga 5%, cutaneous solution
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1. What Minorga 5%, cutaneous solution is and what it is used for

Minorga 5%, cutaneous solution contains minoxidil, at the concentration of 50 mg per ml.

Minorga 5%, cutaneous solution is a medicine in a liquid form, for direct application 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 to renew hair growth is unknown.

Minorga 5%, cutaneous solution is indicated for use in adults aged from 18 to 65 years with a gradual weakening or loss of hair on top of the head. Weakening or loss of hair is a slow process that may become obvious after several years of gradual loss.

Minorga 5%, cutaneous solution is particularly indicated in men who suffer from hair loss or weakening on top of the head and in women with generalized hair weakening.

You must talk to a doctor if you do not feel better or if you feel worse after 4 months.

2. What you need to know before you use Minorga 5%, cutaneous solution

Do not use Minorga 5%, cutaneous solution :

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

Minorga 5%, cutaneous solution is not indicated in cases of alopecia areata (sudden or unexplained hair loss) or scarring alopecia (characterized by skin with healing characteristics, such as burn or ulcers). Also, Minorga 5%, cutaneous solution should not be used if the hair loss is associated with pregnancy, delivery or severe diseases, such as thyroid malfunction, lupus, loss of sections of hair associated with scalp inflammation, or other diseases.

Warnings and precautions

As alopecia can also be a symptom of serious diseases of ovary, hypophysis or suprarenal gland, women should consult a doctor before using Minorga 5% if they suffer from any of the following symptoms: rapid weight gain, particularly of the trunk and face with sparing of the limbs (central obesity); facial male-pattern hair growth (hirsutism); menstrual disorders; hypertension; muscle weakness; back pain; osteoporosis; striae; acne.

Talk to your doctor or pharmacist before using Minorga 5%, cutaneous solution.

You should not initiate the application of Minorga 5%, cutaneous solution if your hair loss is sudden or unexplained or in the event of hair loss after disease or treatment. If you have any further questions regarding hair loss, ask your doctor before using Minorga 5%, cutaneous solution.

Patients receiving treatment with Minorga 5%, cutaneous solution should be previously submitted to a physical examination. The doctor should determine whether the individual has a normal scalp.

If you suffer or have ever suffered from a heart or vascular disease including irregular heartbeat, you should consult a doctor before using Minorga 5%.

You should not apply Minorga 5%, cutaneous solution if the affected area is red and inflamed, irritated or sore, as in the case of a severe sunburn or seborrheic dermatitis.

You should also not apply Minorga 5%, cutaneous solution in other parts of the body or concomitantly with other medicines for topical use.

If you feel unusual symptoms after applying Minorga 5%, cutaneous solution, discontinue the application and talk to your doctor. It is particularly important to stop the application of the medicinal product in the event of increased heart rate (palpitations), swelling of hands and feet, sudden weight gain with no apparent cause, chest pain, weakness and/or dizziness.

You should also discontinue the product application if the scalp is red or irritated. Patients with a history of heart diseases could worsen their condition with the use of Minorga 5%, cutaneous solution.

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.

Do not swallow.

Do not inhale.

Minorga 5%, cutaneous solution contains alcohol in its composition that may cause a sensation of burn and eye irritation. In the event of accidental contact with sensitive surfaces (eye, abraded skin and mucous membranes), the area should be bathed with large amounts of cool tap water.

You should tell your doctor or pharmacist, in case you:

- * suffer from heart diseases
- * have history of allergic reactions
- * are taking other medicines

Children and adolescents

Minorga 5%, cutaneous solution should not be used by patients aged below 18 years old.

Other medicines and Minorga 5%, cutaneous solution

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Although not clinically proven, there is a theoretical possibility that absorbed minoxidil may potentiate orthostatic hypotension in patients concomitantly taking peripheral vasodilators.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Minorga 5%, cutaneous solution should not influence the ability of the patient to drive or use machines.

Minorga 5%, cutaneous solution contains propylene glycol.

It may cause skin irritation.

3. How to use MinorgaA 5%, cutaneous solution

Minorga 5%, cutaneous solution is a treatment and not a cure. To keep or increase the results achieved, it is important not to discontinue the regular application of the medicine as prescribed by your doctor and for your condition.

You should apply one dose of Minorga 5%, cutaneous solution (1 mL) directly on the scalp area in which you are losing hair, TWICE DAILY, for example, in the morning and at night (or other comparable regimens).

Spread the dose over all the affected area, massaging it with the tips of your fingers. Each bottle of Minorga 5%, cutaneous solution contains an amount enough for 30 days. This medicine should not be used by patients aged below 18 years.

Clinical trials have shown that treatment response is quite variable and the results are not immediate. Generally, the growth of new hair is gradual and continuation of the application twice daily for at least 4 months is necessary for it to become noticeable.

As Minorga 5%, cutaneous solution starts to act on the hair follicles, it may be observed a temporary increase of the hair loss rate, about 2-6 weeks after treatment initiation.

If, when initiating treatment with Minorga 5%, cutaneous solution, you had very little hair and you respond to the treatment, your new hair will initially grow soft and velvety, not being very visible. With the continuation of treatment, new hair will acquire color and texture similar to all other hair. If hair loss is not very accentuated when initiating treatment, new hair will grow with color and texture similar to all other hair.

The use of an inappropriate or inappropriately dosed medicine can cause problems. Therefore, you should never use this medicine for the treatment of other diseases or other patients.

While using Minorga 5%, cutaneous solution, there is no need to change standard cares with your hair. However, you should apply Minorga 5%, cutaneous solution first, let your hair dry, and only then apply the “sprays”, mousses, conditioners, gels, or any other product (in case of hair dye, permanent, etc.). If you swim or get your head wet, preferably apply Minorga 5%, cutaneous solution on the dry scalp after swim, or hold two hours after applying the product. You should allow Minorga 5%, cutaneous solution to act on the scalp for at least two hours.

How to apply Minorga 5%, cutaneous solution?

Minorga 5%, cutaneous solution is for External Use only.

Apply, in the hair loss area, one dose (1 mL) twice daily. You should not apply doses higher than those recommended. The medicine should not be applied in other areas beyond the scalp. If you wash your scalp before applying Minorga 5%, cutaneous solution, you should use a soft and efficient shampoo.

Seven sprays are required to release one dose (1 mL) of Minorga 5%, cutaneous solution.

Massage the applied amount throughout the affected area. Wash your hands after each application.

Instructions for use

The instructions for use depend on the type of applicator used.

- A. Spray to apply the solution on large areas of the scalp.
- B. Spray with applicator to apply the solution on small areas of scalp or in the hair.

A. Spray

It is recommended on large areas of scalp.

- 1) Take out the cap of the bottle.
- 2) Place the spray towards the bald area, pressure it once and spread the solution with the tip of the fingers throughout all area. Repeat this procedure six times until complete application of the required dose of 1 mL (i.e. a total of 7 sprays). Avoid inhaling the medicinal product during application.
- 3) Rinse the spray and replace the cap on the bottle after use to avoid the evaporation of alcohol.

B. Spray with applicator

It is recommended on small areas of scalp or in the hair.

- 1) Take out the cap of the bottle.
- 2) Pull the upper part out of the spray, removing it. Adapt the applicator to the spray and make full pressure.
- 3) Place the spray towards the bald area, pressure it once and spread the solution with the tip of the fingers throughout all area. Repeat this procedure six times until complete application of the required dose of 1 mL (i.e. a total of 7 sprays). Avoid inhaling the medicinal product during application.
- 4) Rinse the applicator and replace the cap on the bottle after use to avoid the evaporation of alcohol.

Always use this medicine exactly as described in this leaflet as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you use more Minorga 5%, cutaneous solution than you should

Minorga 5%, cutaneous solution should not be orally administered. In case of accidental intake, talk to your doctor or an anti-poison information center.

Accidental ingestion may produce systemic effects related to minoxidil vasodilator effect.

Signs and symptoms of minoxidil overdose would primarily be cardiovascular effects associated with fluid retention and tachycardia. The fluid retention may be controlled with appropriate diuretic therapy. Tachycardia may be controlled by administration of a beta-adrenergic blocking agent. Symptomatic hypotension should be treated with intravenous administration of saline. Sympathomimetics, such as epinephrine and norepinephrine, should be avoided since these medicinal products cause an excessive heart stimulating effect.

In case other effects related to the use of Minorga 5%, cutaneous solution occur and that are not described in this leaflet, you should tell your doctor or pharmacist immediately.

Clinical trials were carefully conducted to determine the exact amount of Minorga 5%, cutaneous solution to be applied in order to obtain satisfactory results. The application of higher doses than those recommended (1 ml), or more than twice daily, is not recommended. Increasing the dose or the frequency of administration will not make the hair grow faster or in a higher amount and this may cause an increase in the occurrence of undesirable effects.

If you forget to use Minorga 5%, cutaneous solution

If you miss one or two applications of Minorga 5%, cutaneous solution, you should restart its application twice daily, in accordance with the normal scheme. You should not apply a higher dose to make up for the forgotten doses.

If you stop using Minorga 5%, cutaneous solution

To keep the capillary growth, it is necessary to continuously apply the recommended dose of Minorga 5%, cutaneous solution. Approximately three or four months after Minorga 5%, cutaneous solution treatment discontinuation, the growth of new hair will stop and the hair loss process will return to its normal status, as it was before starting the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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).

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects are listed in decreasing order of frequency.

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

- Headache

Common (may affect up to 1 in 10 people)

- Depression
- Dyspnea (shortness of breath)
- Pruritus, hypertrichosis (abnormal amount of hair growth), rash, acneiform rash, dermatitis, inflammatory skin disorder
- Musculoskeletal pain
- Peripheral edema
- Pain

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

- Dry skin, skin exfoliation, temporary hair loss, changes in hair texture, changes in hair color
- Application site irritation

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

- Palpitations, heart rate increased, chest pain
- Application site erythema

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

- Hypotension

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

ADR Reporting - Website: www.medicinesauthority.gov.mt/adrportal.

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

5. How to store Minorga 5%, cutaneous solution

Keep this medicine out of the sight and reach of children.

Flammable product. Protect from heat. Keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the bottle after "EXP.". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Minorga 5%, cutaneous solution contains

- The active substances is minoxidil
- The other ingredients are propylene glycol, ethanol and purified water

What Minorga 5%, cutaneous solution looks like and contents of the pack

Minorga 5%, cutaneous solution is a clear and colorless or slightly yellow solution with an alcohol odor available as follow:

HDPE Bottle with spray pump / applicators containing 60 ml of solution.

Pack sizes:

1 x 60 ml with 1 removable actuator with nozzle and 1 removable actuator with rod.

3 x 60 ml with 3 removable actuators with nozzle and 2 removable actuators with rod.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Autorisation Holder

Laboratoires Bailleul S.A.

14-16 Avenue Pasteur

L-2310 Luxembourg - Luxembourg

Manufacturer

DELPHARM HUNINGUE SAS

26 rue de la Chapelle

68330 Huningue

France

Or

Lichtenheldt GmbH Pharmazeutische Fabrik
Industriestrasse 7-11
23812 Wahlstedt
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus	Androxil 5%, δερματικό διάλυμα
Czech Republic	Minorga 50 mg/ml, kožní roztok
Greece	Androxil 5%, δερματικό διάλυμα
Italy	Minoxidil Biorga 5%, soluzione cutanea
Malta	Minorga 5%, cutaneous solution
Poland	Minorga 50 mg/mL, roztwór na skórę
Portugal	Minoxidil Biorga 5%, solução cutânea
Romania	Minorga 50 mg/mL, soluție cutanată
Slovakia	Minorga 5%, dermálny roztok
Spain	Minoxidil Biorga 50 mg/ml solución cutánea

This leaflet was last revised in 07/2025.

Other sources of information

Detailed information on this medicine is available on the web site of The Medicines Authority.