

## Package leaflet: information for the user

### Minoxidil Linn 50 mg/ml solution for topical use

#### Minoxidil

Read carefully the entire leaflet before you take this goes use because there states important information in for you.

Use this medicine always exactly as described in this leaflet or such as your doctor or pharmacist you that has told.

- Keep this leaflet. You may need it again later ..
- Has you still questions? Then contact your pharmacist.
- Do you experience one of the side effects listed in section 4 listed? Or do you a side effect that not in this leaflet listed? Then contact contact with your your doctor or pharmacist.
- Does your complaint after 6 months not less, or is he even worse? Then contact your doctor.

#### Contents of this leaflet

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#### 1. and what is it used for becomes this medicine used?

Minoxidil Linn is a medication that stimulates hair growth and that available is as solution for topical use of minoxidil (active substance), dosed at 5% (50 mg/ml).

Minoxidil Linn is indicated for the treatment of the 'common' in men occurring baldness (alopecia androgenetica).

Minoxidil Linn is intended for external use and should only be applied to the scalp ..

your hair growth after six months months still not improved? Then contact your doctor.

#### 2. When should you not use this medicine or must you be extra careful with it?

When may you this medicine not use?

- You are allergic to one of the substances in this medication. These substances can you find in section 6.

When must you extra careful be with this medicine?

Contact your doctor or pharmacist before you this medicine used.

Minoxidil Linn is not intended for use in a family history of hair loss, if hair loss sudden and/of irregular occurs, if hair loss the result is of pregnancy or childbirth (this applies only to women), or in unexplained hair loss. Also in cases where hair loss the result is from certain treatments, such as chemotherapy for cancer, or for certain diseases such as iron deficiency, thyroid disorders, problems with the immune system or certain form of syphilis, as well as in severe malnutrition and in certain habits in the external care (e.g.. braiding or tight ponytails) minoxidil must not be used.

You must let your scalp examinations before you start with the treatment with Minoxidil Linn. Your scalp must be healthy be, normal and intact, because if an inflammation or injury (abrasion, psoriasis, sunburn or severe exfoliation) of the skin has, can the absorption of the medication through the skin increased are, which a increased risk of systemic side effects with it entails.

If you suffer from heart problems (lack of blood due to a narrowed or blocked blood vessel (ischemia), disorder in the heart rhythm (arrhythmia), congestive heart failure or heart valve disease), consult then your doctor before you start with the treatment of Minoxidil Linn. You should your doctor to inform about your medical history (previous illnesses, current diseases and medication, allergies, etc.) so that your doctor your condition can assess and/or you can advise about whether the treatment with Minoxidil Linn suitable is. If you start the treatment may begin, should you regularly checked to be by the doctor and should you to know how to recognize of some side effects can identify, such as:

- serious skin reactions
- increased heart rate (tachycardia)
- sudden and unexplained weight gain
- difficulty with breathing (especially at rest)
- lowered blood pressure, in the general and/or at rest
- the development or the worsening of a constricting, pressing, painful sensation on the chest (angina pectoris)
- swelling of the face, hands, ankles or abdomen.

If you one of the aforementioned side effects notice or if you any side effect notice that not in this leaflet listed, stop immediately immediately with the treatment and consult your doctor.

If you simultaneously antihypertensive medications use, you may use Minoxidil Linn only use under medical supervision.

There are cases of excessive hair growth reported on the body of infants after skin contact with the areas where minoxidil was applied by patients (caregivers) who topically applied minoxidil used. The hair growth became within a few months normal again when the children were no longer exposed to minoxidil. Ensure that you do children not in contact come with body parts where you have applied minoxidil topically have applied. Consult a doctor if you excessive hair growth on the body of your child notices during the period that you topically apply to apply products with minoxidil use.

#### Elderly

Minoxidil Linn may not be used by patients older than 65 years, because the safety not established is for this group.

Children en adolescents to 18 years

Minoxidil Linn must not be used by patients younger than 18 years, because the safety not established is for this group.

Do you still other medications?

Do you besides Minoxidil Linn still other medications, do you that recently done or exists the possibility that you in the near future other medications will use ?Tell that then then your doctor or pharmacist.

Tell the your doctor if you apply any of the following medications on the skin before you use Minoxidil Linn use used:

- medicines that tretinoin or other retinoids contain
- medicines for use on the skin that corticosteroids contain or skin-covering ointments, creams or other greasy substances (e.g.. Vaseline).

Do not expose the treated skin to intense sunlight , asskin reactions ( skin reactions (e.g.. erythema) of sunburn can occur and to an increased absorption of minoxidil through the skin can lead.

Pregnancy and breastfeeding

Are you pregnant, do you think you are pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor, before you doctor, before you this medicine used.

Since there no adequate and controlled studies with Minoxidil Linn have been conducted during pregnancy and breastfeeding, is this medicinal product not recommended during these periods.

Driving ability and the use of machines

Minoxidil Linn has no effect on the ability to vehicles to operate and machines to use.

Minoxidil Linn contains propylene glycol. It can cause skin irritation cause.

contains ethanol (alcohol). It can cause irritation irritation, burning sensation and dry skin cause. If it by accident comes into contact with sensitive parts ( eyes, mucous membranes mucous membranes, abraded skin), must the affected area carefully be washed with an abundant amount of running tap water. Consult your doctor if the burning sensation and/or the irritation persists.

### 3. How do you use this medicine ?Use

this medication always always exactly as described in this leaflet or as your doctor or pharmacist has told you .. you are unsure about the correct use use? Then contact your doctor or pharmacist.

Minoxidil Linn is exclusively intended for external use on the scalp.

The recommended dosage is 1 ml Minoxidil Linn twice daily, every 12 hours.

Remove the cap from the bottle. Apply 1 ml Minoxidil Linn solution to, using the sprayer 6 times by pressing press, twice per day, every 12 hours. Apply the solution to the center of the affected area and spread it with your fingertips to make sure of to are that the medication evenly is distributed. Use for a more accurate application the applicator included in the packaging is provided. Remove the upper part of the spray head and place the applicator. Then press the applicator 6 times , as described above. Wash your hands thoroughly after each application.

#### Cleaning of the sprayer and applicator

Remove after each use the upper part of the spray head or applicator and rinse with alcohol to the residues of the product to remove and to blockage to prevent.

#### Precautions for use

Do not more than 1 ml of the solution, regardless the size of the affected area, and apply no more than 2 ml of the solution per day ..

inhalation of the product and and avoid contact with the eyes, mucous membranes and skin affected by abrasion, inflammation or skin lesions. If this does happen, must the affected area carefully be washed with an abundant amount of running tap water. Consult your doctor if the burning feeling and/or the irritation persists.

#### Duration of the treatment

The studies conducted so far show studies indicate that 4 or more months treatment with Minoxidil Linn necessary necessary are for visible hair growth. Interruption of the treatment can within 3 to 4 months return to the initial state resulting in consequence have.

#### Have you too much of this medication used?

There are no cases reported of an overdose minoxidil as result of cutaneous administration of this agent. There can however excessive and undesirable hair growth occur (face, neck, back, chest, abdomen, legs) if there higher doses than recommended are used or if the medication more frequently is applied than recommended, or on other places than the scalp (especially on large areas of the body). In this case must the treatment be interrupted until the normal hair growth is restored (this takes several months required).Increased systemic absorption of minoxidil ( of minoxidilclinically more serious situation situation) can also occur, which a increased risk of systemic side effects with it entails.

Accidental ingestion of Minoxidil Linn of Minoxidil Linn can serious side effects on the entire body cause related to the pharmacological action of minoxidil (e.g.. an increased heart rate, fluid retention in tissue (edema), lowered blood pressure, etc.). Go to suspect of overdose or poisoning with this medicine, immediately to a hospital, for symptomatic treatment.

#### Did you forget to use this medicine ?Did you

forget to use the medication to apply , do it assoon as you remember , unlessit is already almost time for the next application . In that application. In that case, wait until the next application and apply the usual dose , atthe same time ,and resume the normal normal treatment schedule.

Use no double dose to make up for a missed dose in catch up.

Remember however that the success of the treatment depends on the regular basis application of this medication.

Do you have any other questions about the use of this? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medication can also this medication have side effects, although not everyone everyone with it to make.

Take immediately contact with a doctor if you a of the following symptoms notice; possibly have you urgent medical treatment needed:

swelling of the face, the lips or the throat, which makes swallowing or breathing difficult .

This can be a sign of a serious allergic reaction (frequency not known, cannot be determined with the available data cannot be determined).

Very common side effects (side effects in more than 1 in 10 users): Headache ..

side effects common in 1 to 10 out of 100 users):

Shortness of breath (dyspnea),

Itching (pruritus), excessive hair growth (hypertrichosis), (skin) rash, redness (rash), acne-like skin reaction, skin inflammation (dermatitis).

Muscle pain.

Fluid retention in the limbs.

Sometimes occurring side effect (in less than 1 in 100 users): Lowered blood pressure (hypotension).

Rarely occurring side effects (in less than 1 in 1000 users): Increased heart rate (tachycardia), palpitations.

Side effects with frequency 'Not known' (based on the known data cannot the frequency be determined): Hypersensitivity

Hypersensitivity sudden swelling of the skin and mucous membranes) (e.g. of lip, tongue, mouth, throat or face), with as result breathing difficulties and/or itching and skin rash, often as allergic reaction (angio-edema), inflammation of the skin after contact with this substance.

Depressed mood.

Dizziness.

Eye irritation.

Low blood pressure (hypotension).

Nausea, vomiting.

Alopecia (this stops after a few weeks of use of minoxidil and may occur by loss of old and growth of new hair), change in hair color, abnormality in the hair texture, reaction at the site of apply: itching, irritation, pain, (skin) rash, swelling, dry skin, redness, scaling of the skin (exfoliation), dermatitis, blistering, bleeding and ulceration. Pain in the chest.

The reporting of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also to possible side effects that are not listed in this leaflet .. You can side effects also directly report via the Dutch Side Effects Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us help more information to obtain about the safety of this medication.

## 5. How do you store this medicine ?Store

below 25°C. Not in the refrigerator or the freezer store.

Keep the bottle well closed.

Shelf life after opening: 50 days.

Keep out of the sight and reach of children keep.

Do not use this medicine after the expiry date . It is found on the packaging . box or the bottle after "Exp.". There is a month and a year. The last day of that month is the expiry date.

Rinse medicines not through the sink or the toilet and throw them not in the trash can. Ask your pharmacist what you should do with medicines must do that you no longer use. They are then in a responsible manner destroyed and do not enter the environment end up.

## 6. Contents of the packaging and other information

Which substances are in this medicine?

- The active ingredient in this medicine is minoxidil. Each milliliter of the solution contains 50 mg minoxidil.
- The other ingredients in this product are propylene glycol and ethanol (96%).

What does Minoxidil Linn look like and how much is in one packaging?

Clear, colorless to light pink, homogeneous solution.

Minoxidil Linn 50 mg/ml is available in cardboard box with one or three transparent, red bottles of 100 ml, with a spray head and a colorless cap. An applicator is supplied separately in the outer box.

Holder of the license for the in the trade placing and manufacturer

Marketing Authorization Holder

MAE Holding BV

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Netherlands

Manufacturer

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This medication is registered under RVG 122548.

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