

Package leaflet: Information for the patient

Minoxidil 5% w/v cutaneous spray, solution

For men

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. See section 4.
- 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

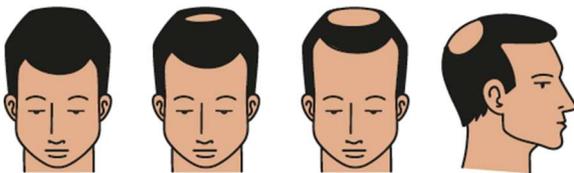
1. What Minoxidil is and what it is used for
2. What you need to know before you use Minoxidil
3. How to use Minoxidil
4. Possible side effects
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1. What Minoxidil is and what it is used for

Minoxidil is a medicine for topical application to the scalp that stimulates hair growth in men aged 18-65 with male-pattern hair loss (men with a family history of hair loss).

The start of hereditary hair loss in men is characterised by the thinning of the frontal hairline at the temples with the formation of a receding hairline. Later on, there is also increasing hair loss on the crown of the head.

The following illustrations show the stages of male-pattern hair loss.



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 Minoxidil

Do not use Minoxidil

- if you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6)
- if you are a female
- if you are under the age of 18 and over the age of 65
- if you are using any other medicines on the scalp
- if you have any kind of dressing or bandage on your scalp
- if you suffer from sudden or uneven hair loss

- if you have any condition that affects your scalp, including psoriasis (an itchy inflammatory skin condition), sunburn, shaved scalp or if your scalp skin is damaged by scars or burns, since no hair roots are present
- if you have total baldness or complete loss of all body hair
- if you have any signs of cardiovascular disease or heart rhythm problems
- if you have suffer from high blood pressure
- if you have a red, inflamed or painful scalp
- if you do not know why you are losing your hair
- if you are not sure if your hair loss is hereditary.

Warnings and precautions

You should not use Minoxidil

- if you have any signs of cardiovascular disease or heart rhythm problems
- if you suffer from high blood pressure
- if you are using medicines to treat high blood pressure (antihypertensive agents).

Talk to you doctor or pharmacist before using Minoxidil

- if you have abnormal hormonal levels, a disease affecting the whole body or a lack of sufficient nutrition in the body. In these cases, your treatment may need to be adjusted
- if you are at all unsure whether your scalp is normal and healthy.

You should stop Minoxidil and consult a doctor

- if you are found to have low blood pressure or if one or more of the following symptoms appear: chest pain, faster heartbeat, weakness or dizziness, sudden and unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp or if other not expected new symptoms appear (see section “If you use more Minoxidil than you should”).

Apply Minoxidil only to a normal healthy scalp. You should not use Minoxidil if the cause of hair loss is not known or if the scalp is red, inflamed or painful.

There is no clinical experience to date regarding its effectiveness for hair loss in the temporal region (receding hairline).

If effects on inner organs (systemic effects) or severe skin reactions occur, the product must be discontinued.

Minoxidil is intended only for external use only on the scalp. Do not apply Minoxidil to other parts of the body.

Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp. Wash your hands thoroughly before and after applying the solution and rinse other areas that have come into contact with the solution.

Isolated cases of slight changes in hair colour have been reported by patients with very fair hair when using hair care products at the same time, or after swimming in heavily chlorinated water.

Accidental ingestion can cause serious side effects on the cardiovascular system. Therefore, you must keep this medicine out of the reach of children.

Avoid breathing in the spray mist.

Minoxidil 5% w/v cutaneous spray, solution is flammable. Do not use near an open flame, lit cigarettes or some devices (e.g. hairdryers).

Children and adolescents

Do not give this medicine to children and adolescents below 18 years as safety and effectiveness in this age group have not been established.

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.

Other medicines and Minoxidil

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 and other agents. Although not clinically proven, there is a theoretical possibility that absorption of the active substance in Minoxidil (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). Guanethidine is an example of an antihypertensive drug that may interact with minoxidil.

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

Pregnancy and breast-feeding

Minoxidil is for use in male patients only. There is only limited experience with the application of Minoxidil during pregnancy. Minoxidil incorporated into the body can pass into breast milk. Thus, Minoxidil must not be used by pregnant women and breast-feeding mothers.

Driving and using machines

This medicinal product may cause dizziness or low blood pressure. If affected, patients should not drive or operate machinery.

Minoxidil contains propylene glycol and alcohol (ethanol 96 per cent)

This medicine contains 350 mg propylene glycol in each ml of solution.

This medicine contains 510 mg of alcohol (ethanol) in each ml of solution. It may cause burning sensation on damaged skin.

Ethanol can cause eye stinging and irritation. In case of accidental contact with sensitive areas (eyes, skin abrasions, mucous membranes), you must rinse these with plenty of water.

If you apply Minoxidil repeatedly on your hair rather than your scalp, this might lead to increased hair dryness and/or stiffness due to the ethanol and propylene glycol content in Minoxidil.

3. How to use Minoxidil

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.

Minoxidil is intended for external use on the dry scalp. Please use Minoxidil only on healthy, undamaged scalp and follow the instructions for use below exactly at all times. Do not apply Minoxidil to body areas other than the scalp.

The recommended dose is:

Apply 1 ml Minoxidil twice daily (morning and evening) to the affected areas in the crown region of the scalp.

The daily amount applied of 2 x 1 ml solution should not be exceeded, regardless of the size of the affected skin area.

Leave at least 12 hours between each use.

Use in children and adolescents

Minoxidil must not be used in children and adolescents below 18 years, as no effectiveness and safety results from controlled studies are available in these age groups.

Method of administration

Minoxidil is intended only for external use and only on the scalp.

Each pack of Minoxidil solution contains 2 different application devices:

- pre-assembled spray-pump for large-area application
- separate applicator with extended tip for smaller areas

Both applicators can be swapped by detaching the one applicator and replacing it with the other.

Prior to applying minoxidil, it must be ensured that the scalp is dry.

Minoxidil should not be applied to other parts of the body.

Instructions for use/application

According to the affected area and the application device provided.

A. Spray pump

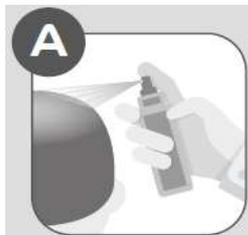


Fig. 1

1. Remove the outer cap of the bottle.
2. Apply 1 ml of solution, by pressing the spray pump 6 times (Fig. 1).

After each pumping action, spread the liquid over the affected area with your fingertips. At the same time, avoid breathing in the spray mist.

For a more localised application (small areas of the scalp or under the hair), use the applicator provided with the pack.

B. Applicator

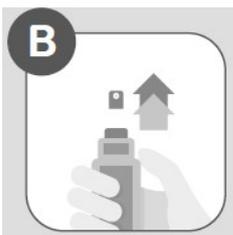


Fig. 2



Fig 3

1. Remove the outer cap of the bottle.
2. Remove the top part of the spray head (piece with the orifice), by pulling it up (Fig. 2), and insert the applicator (Fig. 3 and 4).
3. Apply 1 ml of solution, by pressing the applicator 6 times (Fig. 5).

After each pumping action, spread the liquid over the affected area with your fingertips. At



Fig. 4



Fig. 5

the same time, avoid breathing in the spray mist.

Spray pump and applicator cleaning

Remove the top part of the spray head or applicator and rinse with isopropyl alcohol (70 per cent) after each use to clean the product residues and to avoid clogging. After cleaning, place back the removed parts (either the spray pump and outer cap or the spray-tip applicator).

What else must you bear in mind during use?

Hands should be washed carefully after applying Minoxidil, in order to avoid accidental contact with moist lining of the mouth, nose and eyes.

After applying Minoxidil, you can style your hair as normal. However, you should not moisten the scalp for about 4 hours. This will prevent Minoxidil from being washed off.

Information about increased hair loss

In the treatment of hair follicles with the active substance minoxidil, the resting phase (telogen phase) of the hair cycle is shortened and the growth phase (anagen phase) is reached more quickly. This stimulates new hair growth, which pushes the “old”, no longer active hairs out of the scalp. This gives the initial impression of increased hair loss. In some patients, this reaction has been observed two to six weeks after the start of treatment with the active substance minoxidil. However, there is no need to be alarmed, as this reaction is accompanied by increased hair regrowth. The effect wears off within a few weeks and may be interpreted as a first sign of the minoxidil effect. If hair loss persists for more than 2 weeks, you should stop using Minoxidil and consult your doctor.

Duration of use

The onset and extent of hair growth are different in individual patients. In general, twice-daily treatment for 2 to 4 months is required before an effect is seen. In order to maintain the effect, it is recommended to continue the twice-daily application without interruption.

You will not achieve any better result by applying Minoxidil in larger amounts or more frequently. Regarding a possible therapeutic effect, there is sufficient clinical experience for a treatment period of up to one year.

If no effect is seen after 12 months, treatment should be discontinued.

Please talk to your doctor or pharmacist if you have the impression that the effect of Minoxidil is too strong or too weak.

If you use more Minoxidil than you should

Application of Minoxidil 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.

If swallowed accidentally, the concentration of the active compound minoxidil in Minoxidil 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 signs of overdose, 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 forget to use Minoxidil

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 Minoxidil

It is necessary to continue treatment to improve and maintain hair growth. Otherwise, hair loss will reoccur.

Within 3 to 4 months after interruption of the treatment with Minoxidil the untreated area will look like it did before the treatment started.

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 symptoms - you may need urgent medical treatment:

- Chest pain
- 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).
- Generalised redness of the skin (frequency not known, cannot be estimated from the available data)
- Generalised itching (frequency not known, cannot be estimated from the available data)
- Tightness in the throat (frequency not known, cannot be estimated from the available data)
- Low blood pressure
- Faster heartbeat
- Weakness or dizziness
- Sudden and unexplained weight gain
- Swollen hands or feet
- Persistent redness or irritation of the scalp or if other not expected new symptoms appear

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

- Headache

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

- Itching
- Increased hair growth beyond the scalp (including facial hair growth in women), inflammatory skin reaction (including acneiform rash, skin rash)
- Shortness of breath, difficulty in breathing
- Swollen arms and legs
- Weight gain
- High blood pressure
- Irritation of the scalp such as stinging, burning, dryness, itching, scaling, infected or inflamed hair follicles

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

- Dizziness, nausea

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

- Change in hair texture may occur. If this happens, you should stop using Minoxidil.

Not known (frequency cannot be estimated from the available data):

- Contact dermatitis (allergy-related inflammation of the skin)
- Depressed mood
- Eye irritation
- Faster heartbeat, palpitations, low blood pressure
- Vomiting
- Symptoms at the administration site which may also affect the ears and face, such as itching, skin irritation, pain, redness, swelling, dry skin and inflammatory rash up to possible skin peeling, skin inflammation (dermatitis), blistering, bleeding and ulceration
- Temporary hair loss, changes in hair colour

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Minoxidil

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 carton and bottle after “EXP”. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Keep the bottle tightly closed.

Shelf life after first opening: 1 year.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Minoxidil contains

The active substance is minoxidil. Each millilitre of solution contains 50 mg of minoxidil.

The other ingredients are: propylene glycol and ethanol (96 per cent).

What Minoxidil looks like and contents of the pack

Clear, colourless to yellowish homogeneous solution, free from particles.

The solution is provided in red transparent bottle, closed with a red spray-pump with an applicator.

Pack sizes:

1 x 60 ml and 3 x 60 ml solution

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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