

Package leaflet: Information for the user

Minoxidil 50 mg/ml cutaneous spray, 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 has 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 four months.

What is in this leaflet

1. What Minoxidil 50 mg/ml is and what it is used for
2. What you need to know before you use Minoxidil 50 mg/ml
3. How to use Minoxidil 50 mg/ml
4. Possible side effects
5. How to store Minoxidil 50 mg/ml
6. Contents of the pack and other information

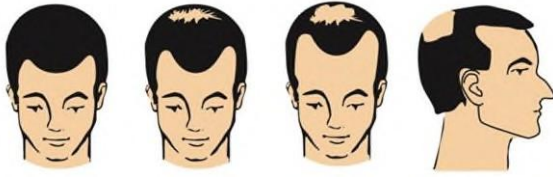
1. What Minoxidil 50 mg/ml is and what it is used for

Minoxidil 50 mg/ml prevents hereditary hair loss in men aged 18 to 65 years and stimulates hair growth. It also promotes the regrowth of new hair on already thinned or bald spots and thickens existing downy hair.

After application, Minoxidil 50 mg/ml penetrates the scalp and reaches the hair roots. It has not yet been possible to clarify the mechanism by which hair growth is stimulated. However, the active substance of Minoxidil 50 mg/ml can stop hereditary hair loss, by:

- increasing the diameter of the hair shaft
- stimulating growth and
- prolonging hair growth phases

However, it will take at least four months before you see any result. If hair roots are still present, fine light downy hair may grow back, which gets longer, denser and darker over time. How fast hair growth starts and how many hairs grow back differs depending on the individual. Large bald spots or hair loss present for more than 10 years are less sensitive to Minoxidil 50 mg/ml. The following illustrations show the stages of male-pattern hair loss, for which it has been possible to demonstrate the effectiveness of minoxidil, the active substance in Minoxidil 50 mg/ml.



Children and adolescents under 18 years, users aged 65 years and older

Minoxidil 50 mg/ml must not be used in children under 18 years and adults aged 65 years and older, as no efficacy and safety results from controlled studies are available in these age groups.

Women

Minoxidil 50 mg/ml should not be used by women. Minoxidil 20 mg/ml is available for women (see also "What you need to know before you use Minoxidil 50 mg/ml).

2. What you need to know before you use Minoxidil 50 mg/ml

Do not use Minoxidil 50 mg/ml

- if you are allergic or have ever had a bad reaction to minoxidil or any of the other ingredients of this medicine (listed in section 6)
- if you are female, as there are occasional signs of cosmetically distressing, reversible, facial hair growth during treatment
- if you are under the age of 18 or over the age of 65
- if you are using any other medicines on the scalp, including creams, ointments or lotions used to treat scalp conditions, e.g.
 - Dithranol – used to treat psoriasis
 - tretinoin – used to treat acne or other skin disorders
 - corticosteroids – a type of anti-inflammatory
 - petrolatum – a common ingredient in hair wax or gel
- 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, or if your scalp skin is damaged by scars or burns, since no hair roots are present
- if you have a shaved scalp
- if you have high blood pressure, even if it is not being treated
- if you have hair loss caused by drug treatment
- if you are not sure if your hair loss is hereditary
- if you have total baldness or complete loss of all body hair
- if the reason for your hair loss is unknown
- if you have a red, inflamed or painful scalp
- if you have signs of cardiovascular disease or heart rhythm problems
- unless you know that your scalp is normal or healthy

If any of these bullet points apply to you now or in the past, get advice from a doctor or pharmacists before using Minoxidil 50 mg/ml

Warnings and precautions

Talk to your doctor or pharmacist before using Minoxidil 50 mg/ml

- if you are at all unsure whether your scalp is normal and healthy
- if you suffer from heart disease, including abnormal heart rhythms or rates, angina or chest pains and / or circulation disorders
- if you are taking any other medicines including:
 - certain blood pressure medicines called 'vasodilators' e.g. hydralazine. There is a potential risk that minoxidil, the active ingredient in Minoxidil 50 mg/ml, may interact with these medicines and increase their effect.

If you are not sure about the medicine you are taking or using, show the bottle or pack to your pharmacist. If any of these bullet points apply now or in the past, **talk to a doctor or pharmacist.**

Hormonal causes, underlying diseases or malnutrition must be excluded. In these cases, you need a specific treatment.

Apply Minoxidil 50 mg/ml only to a normal healthy scalp. You should not use Minoxidil 50 mg/ml 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 50 mg/ml is intended only for external use only on the scalp. Do not apply Minoxidil 50 mg/ml to other parts of the body.

You should not use Minoxidil 50 mg/ml if you

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

You should stop Minoxidil 50 mg/ml 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 50 mg/ml than you should"). There is a chance that the drug could get into the bloodstream if it is over used or if there is a scalp condition such as psoriasis present. Therefore, it is very important that you use your medicine as recommended and follow the instructions very carefully.

Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp.

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.

Avoid contact with the eyes, mouth, broken skin and sensitive areas. If the solution is accidentally applied to areas of the body other than the scalp, rinse thoroughly with plenty of water.

Exceeding the recommended dose will not re-grow your hair any more quickly and you have an increased likelihood of getting side-effects.

Isolated cases of slight changes in hair colour have been reported by users 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.

Exceeding the recommended dose will not re-grow your hair any more quickly and you have an increased likelihood of getting side-effects.

Children and adolescents

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

Other medicines and Minoxidil 50 mg/ml

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 50 mg/ml and other agents. Although not clinically proven, there is a theoretical possibility that absorption of the active substance in Minoxidil 50 mg/ml (minoxidil) into the body may worsen orthostatic hypotension (a drop in blood pressure felt when standing up from a lying position) in users who are also taking peripheral vasodilators (certain high blood pressure medicines which widen the blood vessels), such as guanethidine.

Minoxidil 50 mg/ml should not be used together with creams, ointments or lotions used to treat scalp conditions (e.g. corticosteroids, retinoids, petrolatum (a common ingredient in hair wax or gel) or dithranol) or with agents that increase absorption of the active substance through the skin (skin absorption).

Pregnancy and breast-feeding

Minoxidil 50 mg/ml is indicated for use in male users only. There is only limited experience with the application of Minoxidil 50 mg/ml during pregnancy. Minoxidil incorporated into the body can pass into breast milk. Thus Minoxidil 50 mg/ml must not be used by pregnant women and breastfeeding mothers.

Driving and using machines

This product may cause dizziness or low blood pressure (see section 4.8). If affected, users should not drive or operate machinery.

Minoxidil 50 mg/ml contains propylene glycol (E 1520) and ethanol 96 % (alcohol)

This medicine contains 509 mg propylene glycol (E 1520) in each ml solution.

This medicine contains 248 mg alcohol (ethanol) in each ml 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 50 mg/ml 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 50 mg/ml.

3. How to use Minoxidil 50 mg/ml

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 50 mg/ml is intended for external use on the dry scalp. Please use Minoxidil 50 mg/ml only on healthy, undamaged scalp and follow the instructions for use below exactly at all times. Do not apply Minoxidil 50 mg/ml to body areas other than the scalp.

The recommended dose is:

Apply 1 ml Minoxidil 50 mg/ml twice daily (morning and evening) to the affected areas of the scalp. Leave at least 12 hours between each use. Do not use more than twice a day (your hair will not regrow any more quickly and you may risk side effects).

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

Do not use more than twice a day.

Leave at least 12 hours between each use.

Use in children and adolescents

Minoxidil 50 mg/ml must not be used in children and adolescents below 18 years, as no efficacy and safety results from controlled studies are available in these age groups.

Method of administration

Cutaneous use (scalp).

Each pack of Minoxidil 50 mg/ml contains 2 different pump spray applicators:

- pre-assembled applicator 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.

For the 1 ml dose, 6 spray pumps are needed.

Instructions for use/application:

The solution is sprayed directly onto the scalp within the area of hair loss. For this, press down on the pump six 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.

What else must you bear in mind during use?

Hands should be washed carefully after applying Minoxidil 50 mg/ml, in order to avoid accidental contact with nose, mouth and eyes.

After applying Minoxidil 50 mg/ml, you can style your hair as normal. However, you should not moisten the scalp for about 4 hours. This will prevent Minoxidil 50 mg/ml from being washed off.

The solution is flammable. Do not use while smoking, or near any naked flames or heat source

Duration of use

The onset and extent of hair growth are different in individual users. 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 50 mg/ml 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 4 months, treatment should be discontinued.

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 users, 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.

Please talk to your doctor or pharmacist if you have the impression that the effect of Minoxidil 50 mg/ml is too strong or too weak.

If you use more Minoxidil 50 mg/ml than you should

Application of Minoxidil 50 mg/ml 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 component minoxidil in Minoxidil 50 mg/ml 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 50 mg/ml

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 50 mg/ml

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

If treatment is interrupted, within 3 to 4 months a condition will set in as would have been achieved without treatment with Minoxidil 50 mg/ml.

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.

If you experience any of the following, stop using the medicine and seek immediate medical help:

- Chest pain (frequency not known, cannot be estimated from the available data)
- 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)

If you experience any of the following, stop using the medicine and talk to your doctor:

- Allergic reactions including swollen face, skin redness or itching or throat tightness
- Low blood pressure
- Fast heart beat or an increased awareness of the heart beat (palpitations)
- Faintness or dizziness
- Swollen hands or feet, shortness of breath
- Sudden unexplained weight gain
- Persistent local redness or rash

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

- Headache

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

- Itching or dermatitis
- 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, folliculitis

(small pimples/inflamed spots around the 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 20 mg/ml

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

- 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, altered hair structure
- 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 50 mg/ml

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 freeze.

Contains ethanol which is flammable. Store away from heat, sparks, hot surfaces or naked flames. Do not smoke. Avoid exposure of the container and contents to naked flames during use, storage and disposal. Keep container tightly closed.

Note on shelf life once opened

After opening the bottle, use the solution within 6 weeks.

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 50 mg/ml contains

The active substance is: minoxidil.
1 ml solution contains 50 mg minoxidil.

The other ingredients are: ethanol 96% (v/v), propylene glycol (E 1520), purified water.

What Minoxidil 50 mg/ml looks like and contents of the pack

Minoxidil 50 mg/ml is a clear, colourless to pale yellow solution and is available in packs with 60 ml and 3 x 60 ml cutaneous solution filled in white HDPE bottles.
Each pack contains 2 different applicators, a pre-assembled pump spray applicator and an applicator with extended tip.

Marketing Authorisation Holder and Manufacturer

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