

Package Leaflet: Information for the patient

Minoxidil Torrent 50 mg/ml 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 four months.

What is in this leaflet

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

1. What Minoxidil Torrent is and what it is used for

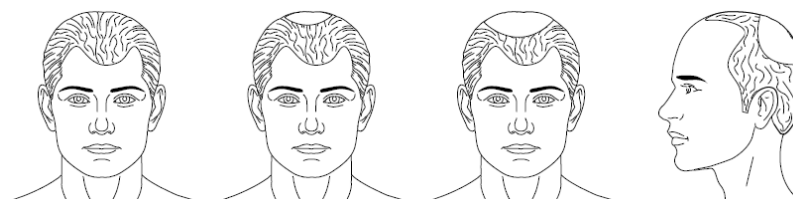
Minoxidil Torrent contains the active substance minoxidil and is a medicine used to treat male pattern hair loss (androgenetic alopecia).

Minoxidil Torrent stabilizes the course of hereditary hair loss (androgenetic alopecia) in the tonsure area of the scalp with a diameter of 3 - 10 cm in men aged 18 - 49 years.

The treatment can counteract the progression of hereditary hair loss. The onset and extent of this effect can vary from person to person and cannot be predicted.

The onset of androgenetic alopecia in men is characterized by the receding of the forehead-hair border at the temples resulting in a receding hairline. Subsequently, there is also increasing hair thinning in the crown region (tonsure area).

The following images show the stages of hereditary hair loss.



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

2. What you need to know before you use Minoxidil Torrent

Do not use Minoxidil Torrent

- if you are allergic to minoxidil or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman, due to occasional signs of cosmetically disturbing, reversible, facial hair growth during treatment.
- if you use other medicines on the scalp.
- if you suffer from sudden or uneven hair loss.

Warnings and precautions

Please talk to your doctor or pharmacist before using Minoxidil Torrent.

- Hormonal causes, underlying diseases or a malnutrition must be ruled out. In these cases you need to receive targeted treatment. You should not use Minoxidil Torrent if the cause of hair loss is unknown or if the scalp is red, inflamed or painful. There is no clinical experience with its effectiveness for hair loss in the temple area (receding hairline).
- Use Minoxidil Torrent only on normal, healthy scalp.
- Minoxidil Torrent is intended for external use on the scalp only. Do not apply Minoxidil Torrent to other parts of the body.

You should not use Minoxidil Torrent

- if you have signs of cardiovascular disease or cardiac arrhythmias are present
- if you suffer from high blood pressure
- if you use medicines to treat high blood pressure (antihypertensives).

You should stop using Minoxidil Torrent and consult a doctor,

- if a decrease in blood pressure is detected, or
- if one or more of the following occurs: chest pain, rapid heartbeat, feeling weak or dizzy, sudden and unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp (see section 3 “If you have used more Minoxidil Torrent than you should”) or other unexpected new symptoms.

You will not get a better result if you use Minoxidil Torrent in larger quantities or more often.

To maintain the effect, it is recommended to continue the use twice daily. If you stop using minoxidil, hair loss will occur again.

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.

Notes on increased hair loss after starting use

When hair follicles are treated with the active ingredient minoxidil, the resting phase (telogen phase) of the hair cycle is shortened and the growth phase (anagen phase) is reached more quickly. This stimulates the growth of new hair. These push the “old” hair that is no longer active out of the scalp. The initial impression is of increased hair loss. This reaction has been observed in some patients two to six weeks after starting treatment with minoxidil. This accelerated hair loss, which is accompanied by increased hair regrowth, disappears within a few weeks and can be the first sign of minoxidil’s effect.

Notes

Applying minoxidil to areas of the body other than the scalp may cause unwanted hair growth.

Occasionally, patients with very light hair have reported minor changes in hair colour (slight blonde discolouration) when using hair care products at the same time or after swimming in water with a high concentration of chlorine.

If you repeatedly apply Minoxidil Torrent to the hair instead of the scalp, this could lead to increased dryness and/or stiffness of the hair due to the ingredients in Minoxidil Torrent.

If you accidentally come into contact with sensitive areas (eyes, abrasions, mucous membranes), you must rinse these areas with plenty of cold water.

Avoid inhaling the spray vapours.

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

Children and adolescents

Minoxidil Torrent must not be used in children and adolescents under the age of 18, as there are no results on effectiveness and safety from controlled clinical studies for this patient group.

Other medicines and Minoxidil Torrent

Tell your doctor or pharmacist if you are taking/using any other medicines, have recently taken/used any other medicines, or might take/use any other medicines.

There is currently no evidence of interactions between Minoxidil Torrent and other products.

Changing from lying or sitting to standing (change of position) can cause a drop in blood pressure. Although not clinically proven, there is theoretically the possibility that this effect is increased by absorption of the active ingredient minoxidil into the bloodstream. This can occur particularly in patients who are simultaneously taking vasodilator medications.

You should not take Minoxidil Torrent together with other dermatics (preparations to be used externally with active ingredients such as e.g. corticosteroids, retinoids, dithranol) or with agents that increase active ingredient absorption through the skin.

Pregnancy and breast-feeding

Minoxidil Torrent is only indicated for use in male patients. Minoxidil Torrent must not be used by pregnant women and nursing mothers as there are no studies on pregnant women and minoxidil can pass into breast milk.

Driving and using machines

Side effects of Minoxidil Torrent may include dizziness or low blood pressure. If this happens to you, do not drive or use machines.

Minoxidil Torrent contains ethanol

This medicine contains 257.2 mg of ethanol (96 per cent) per 1 ml solution.
It may cause burning sensation on damaged skin.

Minoxidil Torrent contains propylene glycol

This medicine contains 518 mg of propylene glycol per 1 ml solution.

3. How to use Minoxidil Torrent

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

The recommended dose is:

Apply 1 ml of Minoxidil Torrent twice a day (morning and evening) to the affected areas in the tonsure area of the scalp.

The amount of 1 ml solution used twice daily should not be exceeded, regardless of the size of the affected skin area.

For the dose of 1 ml, 6 sprays (pump sprays) are needed.

Use in children and adolescents

Minoxidil Torrent must not be used in children and adolescents under the age of 18, as there are no results on effectiveness and safety from controlled clinical studies for this patient group.

Method of administration

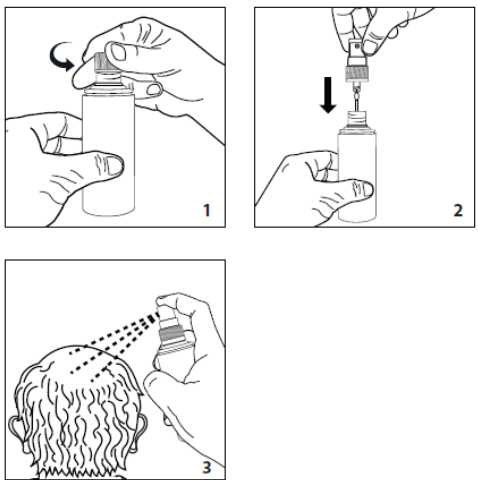
Minoxidil Torrent is intended only for external use and only on the scalp.

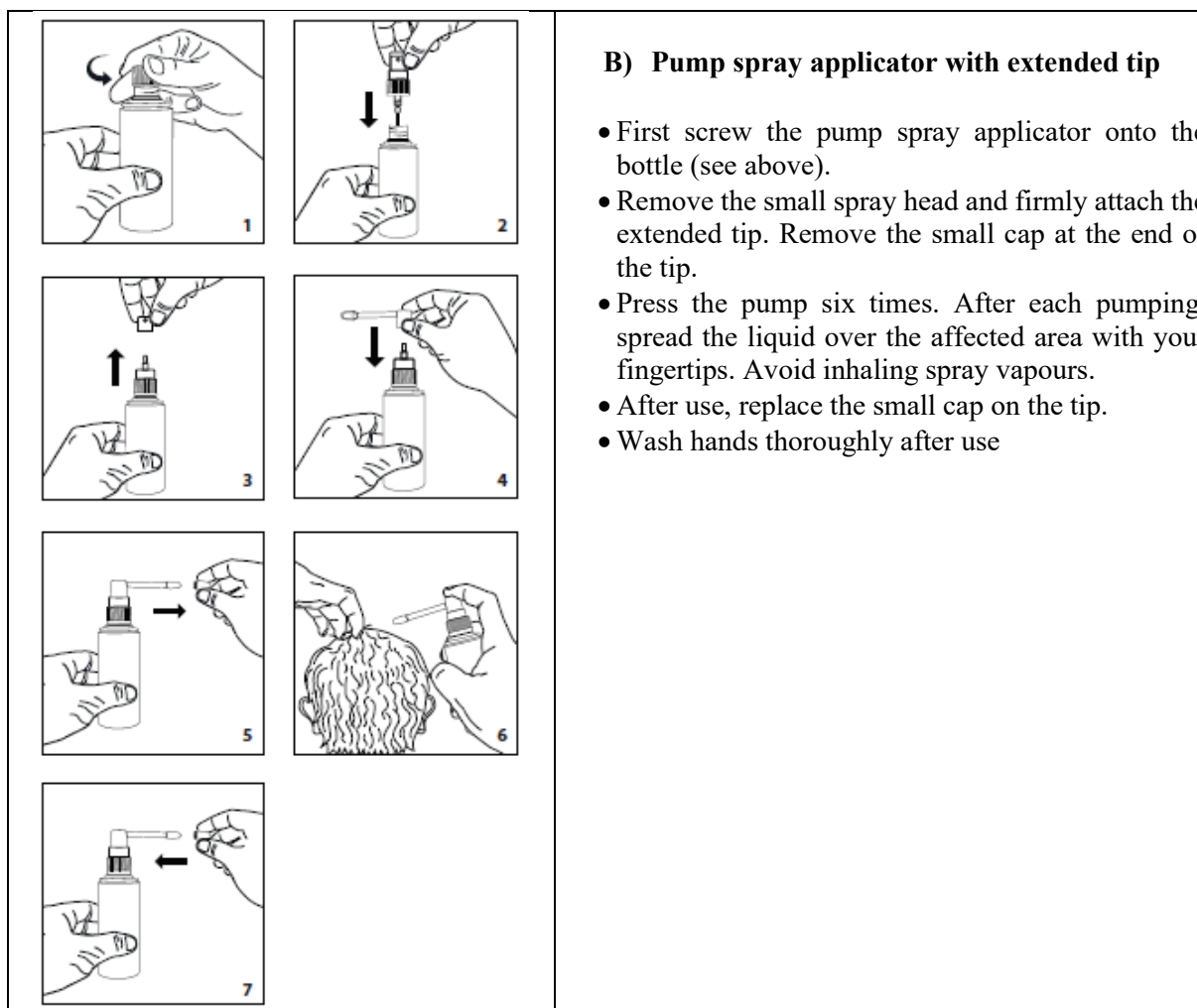
Each pack includes two applicators:

- Pump spray applicator for large areas of the scalp.
- Pump spray applicator with an extended tip for small bald areas.

Instructions for use/application:

The container when fitted with pump spray applicator or pump spray applicator with extended tip, needs to be primed by actuating 6 times before you apply your dose.

 The diagram consists of three numbered illustrations. Illustration 1 shows a hand unscrewing a cap from a bottle. Illustration 2 shows a hand attaching a pump spray applicator to the bottle. Illustration 3 shows a hand spraying the liquid onto a person's scalp.	A) Pump spray-Applicator • Unscrew the screw cap from the bottle. • Place the spray applicator on the bottle and screw it tight. Remove the small cap. • Press the pump six times. After each pumping, spread the liquid over the affected area with your fingertips. Avoid inhaling spray vapours. • Close the spray applicator with the small cap after use. • Wash hands thoroughly after use.
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Cleaning the spray pump and applicator:

To avoid clogging, keep the spray pump applicator capped with the supplied transparent dust cap after every use. If spray pump applicator with extended tip is used, cap the extender with the supplied cap after every use.

In case of clogging, remove the top of the spray pump applicator or spray pump applicator with extended tip and rinse with isopropyl alcohol (50-70%). After cleaning, reinstall the removed parts (either the spray pump applicator or spray pump applicator with extended tip).

What else do you need to pay attention to when using it?

Since Minoxidil Torrent contains alcohol, it is highly flammable. Keep Minoxidil Torrent away from open flames or other sources of ignition.

Minoxidil Torrent is to be applied to the dry tonsured area of the scalp.

Minoxidil Torrent should not be used on other parts of the body.

After applying Minoxidil Torrent, hands should be washed carefully to avoid accidental contact with mucous membranes and eyes.

After applying Minoxidil Torrent, you can style your hair as usual. However, you should not wet the scalp for about 4 hours.

This will help prevent Minoxidil Torrent being washed off.

Duration of use

The onset and extent of hair growth varies between individual patients. Generally a twice daily treatment over 2 to 4 months is required before an effect is noticeable. If there is no effect after 4 months, treatment should be stopped. There is currently sufficient clinical experience about the effectiveness of the solution for up to 12 months.

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

If you use more Minoxidil Torrent than you should

The use of Minoxidil Torrent for men has shown no evidence of a correspondingly large absorption of the active ingredient minoxidil into the bloodstream, which could have an effect on the entire body. If you follow the instructions for use, an overdose is unlikely.

A greater absorption of the active ingredient contained in Minoxidil Torrent into the bloodstream can have effects on the whole body, e.g.. by:

- incorrect use (in higher doses than recommended and on larger areas of the body or other areas of the body than the scalp),
- patient-specific differences,
- unusual sensitivity or impairment of the skin due to inflammation or abnormal skin changes on the scalp (e.g. skin abrasions or psoriasis on the scalp).

After accidentally swallowing or after applying Minoxidil Torrent to damaged or pathological areas of skin, effects on the entire body can occur (systemic effects). This can cause the following side effects to occur: rapid heartbeat, lower blood pressure, accumulation of fluid and therefore sudden weight gain, dizziness, sluggishness.

In case of accidental ingestion or if there are signs of overdose, you should consult a doctor. In the event of an overdose of the active ingredient minoxidil, the doctor can initiate symptomatic and supportive treatment.

If you forget to use Minoxidil Torrent

Do not apply twice as much to make up for a forgotten application. Continue treatment at the recommended dose. Repeating the omitted application is not advisable and could lead to undesirable effects.

If you stop using Minoxidil Torrent

If the treatment is interrupted, a condition will arise within 3 to 4 months that would have been achieved without therapy with Minoxidil Torrent.

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

4. Possible side effects

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

Stop taking Minoxidil Torrent and contact a doctor immediately if you experience any of the following symptoms - you may need urgent medical treatment (frequency not known, cannot be estimated from available data):

- Swelling of the face, lips or throat that impedes swallowing or breathing. This could be a sign of a severe allergic reaction.

- Hypersensitivity reactions with symptoms such as general itching, widespread skin rash and tightness in the throat

Other possible side effects:

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

- headache

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

- weight gain
- increased facial hair growth
- itching, redness and rash
- shortness of breath
- swelling of arms and legs
- high blood pressure
- scalp irritation such as stinging/burning, dryness/itching/dandruff; hair follicle inflammation

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

- dizziness
- nausea

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

- contact dermatitis
- depressed mood
- eye irritation
- rapid heartbeat, palpitations, low blood pressure
- vomiting
- discomfort at the administration site, which may also affect the ears and face, such as: itching, skin irritation, pain, skin redness, swelling, dry skin and inflammatory skin rash, peeling skin, skin inflammation (dermatitis), blistering, bleeding and ulceration.
- temporary hair loss, changes in hair colour, changed hair structure
- chest pain

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 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 Minoxidil Torrent

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.

Shelf life after first opening:

1 month.

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 Torrent contains

The active substance is minoxidil. Each millilitre of solution contains 50 mg of minoxidil. One ml is equivalent to 6 sprays (if using the pump).

- The other ingredients are : ethanol (96 per cent), propylene glycol and purified water.

What Minoxidil Torrent looks like and contents of the pack

Minoxidil Torrent is a cutaneous spray, solution (Spray)

Minoxidil Torrent is a clear, colourless to light yellow solution in a white HDPE bottle with screw closure and black over cap.

Pack sizes: 1 x 60 ml and 3 x 60 ml solution.

Not all pack sizes may be marketed.

Each pack contains 2 different applicators certified as medical device (CE): pump spray applicator with extended tip and pump spray applicator.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (Malta) Ltd.
HHF 028 Hal Far Industrial Estate
Birzebbuga BBG 3000
Malta.

Manufacturer

Heumann Pharma GmbH & Co. Generica KG
Suedwestpark 50,
Gebersdorf
Nuremberg, Bavaria 90449,
Germany

Torrent Pharma (Malta) Ltd.
HHF 028 Hal Far Industrial Estate
Birzebbuga BBG 3000
Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Germany: Minoxidil HEUMANN 50mg/ml Spray zur Anwendung auf der Haut (Kopfhaut), Lösung
Malta: Minoxidil Torrent 50 mg/ml cutaneous spray, solution
Poland: Minoxidilum Torrent

This leaflet was last revised in August 2025.