SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Minoxidil Torrent 50 mg/ml cutaneous spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect:
257.2 mg ethanol (96 per cent) per 1 ml solution.
518 mg propylene glycol per 1 ml solution.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution. (Spray)

Clear, colourless to light yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Minoxidil Torrent stabilises the progression of congenital hair loss (androgenetic alopecia) in the tonsure area of the scalp from 3 - 10 cm in diameter in men aged 18 - 49 years.

The treatment can thus counteract the progression of androgenetic alopecia. The onset and extent of this effect may be individually different and cannot be predicted.

4.2 Posology and method of administration

Posology

Men from 18 to 49 years
1 ml of Minoxidil Torrent should be applied twice daily (morning and evening) to the affected areas of the scalp.

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

For a 1 ml dose, 6 sprays are needed.

Paediatric population
The safety and efficacy of Minoxidil Torrent in children and adolescents below 18 years has not been established. No data are available.

Minoxidil Torrent should not be used in children and adolescents under 18 years of age.

Method of administration

Minoxidil Torrent should only be used on the scalp.

Due to the flammability caused by the alcohol, the container must be kept away from open flames and other sources of ignition.

Before Minoxidil Torrent is applied, ensure the scalp is dry. Minoxidil Torrent must not be applied to other body parts. Hands should be washed thoroughly after application to avoid accidental contact with mucous membranes and eyes. After application of Minoxidil Torrent, hair can be styled, but the scalp must remain dry for about 4 hours to prevent washing off.

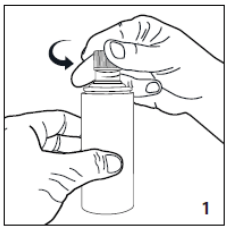
Each pack includes two applicators:

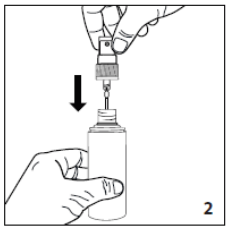
- Pump spray applicator for large areas of the scalp.
- Pump spray applicator with an extended tip for small bald areas.

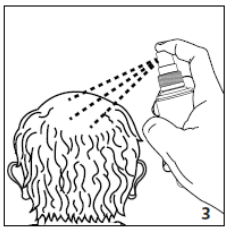
Instructions for use:

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.

Instructions for use for the applicators:

<table>
<tr>
<td> 




</td>
<td>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.</td>
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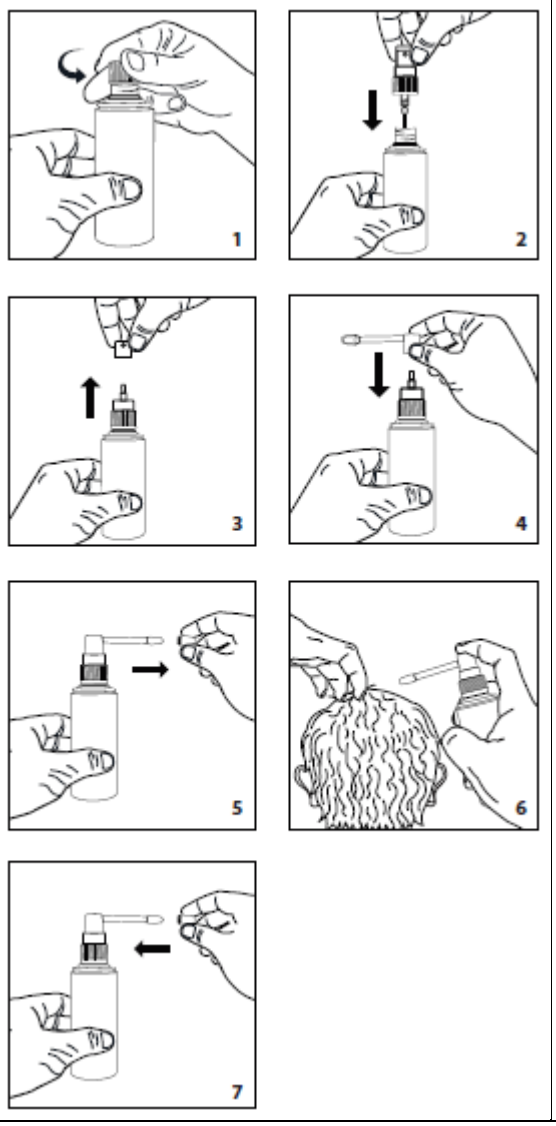

B) Pump spray applicator with extended tip

- First screw the pump spray applicator onto the bottle (see above).
- Remove the small spray head and firmly attach the extended tip. Remove the small cap at the end of the tip.
- Press the pump six times. After each pumping, spread the liquid over the affected area with your fingertips. Avoid inhaling spray vapours.
- After use, replace the small cap on the tip.
- Wash hands thoroughly after use

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).

Duration of use

The onset and extent of hair growth are different in individual patients.
In general, twice-daily treatment is required for 2 to 4 months before an effect is seen. To maintain the effect, it is recommended to continue the twice-daily application continuously. You will not achieve any better result by applying Minoxidil Torrent in larger amounts or more often. Currently, there is sufficient clinical experience on the efficacy of the solution when used for up to 52 weeks.
If the desired treatment success is not achieved within 4 months, the therapy should be discontinued.

4.3 Contraindications

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- women, due to occasional signs of cosmetically disturbing, reversible, facial hair growth during treatment
- use of other topical medicinal products on the scalp
- sudden or uneven hair loss

4.4 Special warnings and precautions for use

Before treatment with Minoxidil Torrent, the patient should be thoroughly examined and his medical history clarified.

Endocrinological causes, underlying systemic diseases or malnutrition must be excluded. In these cases, specific treatment should be initiated if necessary.

Minoxidil Torrent should not be used if the cause of the hair loss is unknown, if the scalp is infected or if the scalp is red, inflamed or painful. The patient should have a normal, healthy scalp.

Minoxidil Torrent is intended for external use on the scalp only. Minoxidil Torrent should not be applied to other parts of the body.

Treatment with Minoxidil Torrent should not be given to patients with signs of cardiovascular disease or cardiac arrhythmias and to hypertensive patients including those treated with antihypertensive drugs.

The patient should discontinue the product and seek medical attention if a decrease in blood pressure is detected or if one or more of the following occur: chest pain, accelerated heartbeat, feeling of weakness or dizziness, sudden unexplained weight gain, swollen hands or feet, persistent redness or irritation of the scalp or if other unexpected new symptoms occur (see section 4.8).

To maintain the effect, treatment must be continued continuously. After discontinuation of minoxidil, hair loss occurs again.

Within the first 2 to 6 weeks of treatment, there may be a temporary increase in the number of hairs that fall out. This effect is due to the fact that the resting phase (telogen phase) of the hair cycle is shortened in hair follicles treated with minoxidil and the growth phase (anagen phase) is reached more quickly. This stimulates the growth of new hairs, which push out the “old” hairs that are no longer active out of the scalp. This initially gives the impression of increased hair loss. However, this is accompanied by an increased regrowth of hair. The effect recedes within a few weeks and can be interpreted as the first sign of the minoxidil effect.

If minoxidil is applied to areas of the body other than the scalp, unwanted hair growth may occur there. Occasionally, patients with very light hair have reported slight changes in hair colour (light blonde) after using hair care products at the same time or after swimming in highly chlorinated water.

Repeated application of Minoxidil Torrent to the hair instead of the scalp could lead to increased dryness and/or stiffness of the hair due to the ingredients in Minoxidil Torrent.

In case of accidental contact with sensitive areas (eyes, skin abrasions, mucous membranes), these must be rinsed with plenty of cold water.

Inhalation of the spray vapours should be avoided.

Inadvertent ingestion may cause severe cardiovascular side effects. Therefore, this medicinal product must be kept out of the reach of children.

Paediatric population
Minoxidil Torrent should not be used in children and adolescents under 18 years of age, as no results on efficacy and safety from controlled clinical trials are available for this patient group.

Minoxidil Torrent contains ethanol (96 per cent).
It may cause burning sensation on damaged skin.

Hypertrichosis in children following inadvertent topical exposure to minoxidil:
Cases of hypertrichosis have been reported in infants following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hypertrichosis was reversible, within months, when infants were no longer exposed to minoxidil. Contact between children and minoxidil application sites should therefore be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

To date, no information is available on interactions between Minoxidil Torrent and other agents. Although not clinically proven, there is a theoretical possibility that absorbed minoxidil may increase orthostatic hypotension in patients taking concomitant peripheral vasodilators.

Minoxidil Torrent should not be used on the scalp with other dermatics or with substances that enhance skin absorption.

Pharmacokinetic drug interaction studies in humans showed that percutaneous absorption of minoxidil is enhanced by tretinoin and dithranol due to increased permeability of the stratum corneum. Betamethasone dipropionate increases the local tissue concentration of minoxidil and decreases the systemic absorption of minoxidil.

4.6 Fertility, pregnancy and lactation

Minoxidil Torrent is indicated for use in male patients only.

Pregnancy
There are no conclusive controlled studies in pregnant women.

Studies in animals have shown an increased risk to the fetus at doses much higher than those intended for human use. There is also a small risk to the human fetus (see section 5.3).

Breastfeeding
Systemically absorbed minoxidil passes into breast milk.

Fertility
After subcutaneous administration (at a multiple of the human dose), a decrease in the conception rate was observed in animals (see section 5.3). Due to the low systemic exposure after topical application, this finding is probably not relevant for the therapeutic use of Minoxidil Torrent.

4.7 Effects on ability to drive and use machines

Dizziness or hypotension may occur as adverse reaction of minoxidil (see section 4.8). Affected patients must not actively participate in road traffic or operate machinery.

4.8 Undesirable effects

The following frequencies are used for the evaluation of adverse reactions:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (frequency cannot be estimated from the available data)

The table below contains data on side effects from a placebo-controlled study of 5 % minoxidil topical foam once daily in women, from a placebo-controlled study of 5 % minoxidil foam twice daily in men, and from 7 placebo-controlled studies in men and women treated with topical minoxidil solution (2 % and 5 %).

System Organ Class	Frequency	Adverse reaction
Nervous system disorders	Very common	Headache
Vascular disorders	Common	Hypertension
Respiratory, thoracic and mediastinal disorders	Common	Dyspnoea
Skin and subcutaneous tissue disorders	Common	Dermatitis, acneiform dermatitis, rash, hypertrichosis, itching Local adverse reactions on the scalp: stinging / burning, itching, dryness / flaking and folliculitis Facial hypertrichosis
General disorders and administration site conditions	Common	Peripheral oedema
Investigations	Common	Weight increased

In the active-controlled study with 5 % minoxidil foam once daily and 2 % minoxidil solution twice daily in women, facial hypertrichosis was observed in both treatment groups.

Post marketing side effects
Additional side effects observed with Minoxidil formulations (including 2 % solution, 5 % solution and 5 % foam in men and women) since market launch are shown in the table below. The common categories of side effects are based
1) on their incidence in appropriately conducted clinical studies or epidemiological studies, if available or
2) their commonality is listed as “Not Known” if none commonalities exist.

System Organ Class	Frequency	Adverse effects
Immune system disorders	Not known	Allergic reactions, including angioedema (with symptoms such as oedema of the lips, mouth, tongue and throat, swelling of the lips, tongue and oropharynx)

		Hypersensitivity reactions (including facial oedema, generalized rash, general itching, facial swelling and tightness in the throat)
		Contact dermatitis
Psychiatric disorders	Not known	Depressive mood
Nervous system disorders	Uncommon	Dizziness
Eye disorders	Not known	Eye irritation
Cardiac disorders	Not known	Tachycardia, Palpitations
Vascular disorders	Not known	Hypotension
Gastrointestinal disorders	Uncommon	Nausea
	Not known	Vomiting
Skin and subcutaneous tissue disorders	Not known	Discomfort at the application site that may also affect the ears and face, such as itching, skin irritation, pain, Reddening of the skin, oedema, dry skin and inflammatory rash up to exfoliation, dermatitis, blistering, bleeding and ulceration. Temporary hair loss. Changes in hair colour. Changes in hair structure
General disorders and administration site conditions	Not known	Chest pain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows a continuous monitoring of the risk/benefit ratio of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via http://www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

The use of Minoxidil Torrent has given no indication of a correspondingly high absorption of the active ingredient minoxidil, which could lead to a systemic effect. If the instructions for use are followed, an overdose is unlikely.

Increased absorption of the active ingredient contained in Minoxidil Torrent due to incorrect application (e.g. application in higher doses than recommended and to larger body surfaces or body surfaces other than the scalp), patient-specific differences, unusual sensitivity or impairment of the skin barrier due to inflammation or pathological skin changes of the scalp (e.g. skin abrasions or dandruff patches on the scalp) may lead to systemic effects.

After inadvertent swallowing, systemic effects may occur due to the active ingredient concentration of minoxidil in Minoxidil Torrent corresponding to the pharmacological effect of the active ingredient (2 ml Minoxidil Torrent contains 100 mg minoxidil, which corresponds to the maximum recommended daily dose for the treatment of hypertension).

Due to the systemic effects of minoxidil, the following side effects may occur:
Cardiac disorders: accelerated heartbeat, hypotension, lethargy
General disorders: fluid accumulation resulting in sudden weight gain.
Nervous system disorders: dizziness

Treatment
In case of overdose with minoxidil, symptomatic and supportive treatment should be given. Clinically significant tachycardia can be controlled with ß-blockers and oedema with diuretics.

Excessive hypotension can be treated by intravenous infusion of physiological saline.
Sympathomimetics such as adrenaline and noradrenaline should be avoided due to their excessive cardiostimulant effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatological preparations; other dermatologicals.
ATC code: D11AX 01

Mechanism of action
Topical minoxidil stimulates hair growth in patients with early to moderate hair loss (androgenetic alopecia). The exact mechanism of action by which minoxidil stimulates hair growth is not fully known. However, minoxidil can stop hair loss in androgenetic alopecia by:

- increasing the diameter of the hair shaft
- stimulating hair growth in the anagen phase
- prolonging the anagen phase
- shortening the telogen phase, thus reaching the anagen phase more quickly.

Pharmacodynamic effects
As a peripheral vasodilator, minoxidil increases microcirculation at the hair follicles. Minoxidil stimulates vascular endothelial growth factor (VEGF), which is thought to be responsible for the increased capillary permeability, indicating a strong metabolic activity seen in the anagen phase.
Upon systemic absorption, minoxidil acts as a peripheral vasodilator (see section 4.9 Overdose).

During clinical trials of Minoxidil Torrent in normotensive and hypertensive patients, no systemic effects were observed due to the low minoxidil absorption, which is on average 1.7% of the applied amount of active ingredient. In clinical studies, a mean serum concentration of 1.6 ng/ml was measured in patients treated with Minoxidil Torrent. In pharmacological studies in a haemodynamically sensitive population of subjects with low-grade untreated hypertension, small effects on heart rate were only measurable above a serum concentration of 21.7 ng/ml.

5.2 Pharmacokinetic properties

Absorption
About 1 - 2 % of a topically administered minoxidil solution is absorbed systemically, compared to 90 - 100 % of oral formulations.
In a study in men, the AUC of the minoxidil serum concentration for the 2% solution averaged 7.54 ng * h/ml compared to an average AUC of 35 ng * h/ml for 2.5 mg of an oral formulation. The mean plasma concentration (C_{max}) for the topical solution was 1.25 ng/ml vs. 18.5 ng/ml after oral administration of 2.5 mg.

In another study in men, the systemic absorption of a 5% foam formulation was about half that of a 5% solution. The mean AUC_{0-12h} and C_{max} for the 5% foam of 8.81 ng * h/ml and 1.11 ng/ml, respectively, was about 50% of the AUC_{0-12h} and C_{max} for the 5% solution of 18.71 ng * h/ml and 2.13 ng/ml, respectively.

The time to maximum plasma concentration (T_{max}) for the 5 % foam of 5.42 h was comparable to the T_{max} of the solution of 5.79 h. A haemodynamic effect of minoxidil is not evident up to an average serum concentration of 21.7 ng/ml.

Distribution
In vitro ultrafiltration showed reversible binding to plasma proteins between 37 - 39 %.

Since only about 1 - 2 % of topically administered minoxidil is absorbed, the extent of plasma protein binding in vivo after topical application is not clinically significant.
The volume of distribution after intravenous administration of 4.6 mg and 18.4 mg minoxidil was 73.1 l and 69.2 l, respectively.

Biotransformation
After topical administration, approximately 60 % of the absorbed minoxidil is metabolised to glucuronides, mainly via the liver.

Elimination
The half-life of topical minoxidil is 22 hours compared to 1.49 hours for oral dosage forms. 97 % of minoxidil is excreted in the urine and 3 % in the faeces.
The renal clearance of minoxidil and its glucuronides based on data from oral dosage forms averages 261 ml/min and 290 ml/min, respectively.

After cessation of treatment, approximately 95 % of topically applied minoxidil is excreted within 4 days.

5.3 Preclinical safety data

Preclinical studies showed no hazard to humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or carcinogenic potential.

Teratogenicity
Reproductive toxicity studies in rats and rabbits with very high exposure rates compared to the intended exposure for humans, have shown evidence of maternal toxicity and risk to the fetus. There is a low risk to the human fetus.

Fertility
Minoxidil doses greater than 9 mg/kg (at least 25 times the human exposure) administered subcutaneously to rats were associated with reduced conception and implantation rates, as well as a reduction in the number of viable young.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

ethanol (96 per cent)
propylene glycol
purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
Shelf life after first opening: 1 month.

6.4 Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and contents of container

60 mL HDPE opaque white round bottle with screw PP white closure with PE Gasket and black over PP cap. Screw on pump with dip tube, actuator and cap which are made of several plastic materials like PE-L, PE, PP and stainless steel and a separate white PP extended actuator with blue cap is included in the packaging.

The medicinal product Minoxidil Torrent contains two applicators certified as medical device (CE): Pump spray applicator with extended tip and Pump spray applicator.

Pack sizes: 1 x 60 ml and 3 x 60 ml solution in a carton box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

MA1504/01801

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 29th August 2025

10. DATE OF REVISION OF THE TEXT

29-08-2025