To be sold by retail on the prescription of a Dermatologist only.

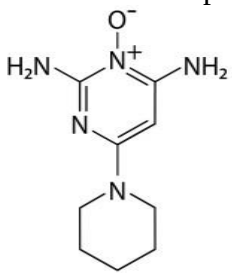
Hairjoy Foam
(Minoxidil Topical Foam 5% w/w)

COMPOSITION

Contains:
Minoxidil IP.....5 % w/w
In aqueous base.....q.s.
Propellant De-odorised LPG…….....q.s.
(Propane,Isobutane,Butane)
Other inavtive ingredients are Aminexil, Butylated hydroxyl toluene, Glycerin, Lactic Acid, Acetyl alcohol, Stearyl alcohol, Cetearth-20, Polysorbate, hexylene glycol, Potassium hydroxide.

DESCRIPTION

Minoxidil is an antihypertensive vasodilator medication also claiming to slow or stop hair loss and promote hair regrowth. Minoxidil occurs as a white to off-white, crystalline powder, soluble in alcohol and propylene glycol; sparingly soluble in methanol; slightly soluble in water; practically insoluble in chloroform, acetone and ethyl acetate. The chemical name for Minoxidil is 2,4-Pyrimidinediamine, 6-(1-piperidinyl)-, 3-oxide. Its molecular formula is C9H15N5O and molecular weight is 209.25. The structural formula is represented below:



Product description:
Hairjoy Foam: White to light yellow colored foam.

INDICATIONS

Minoxidil 5% w/w cutaneous foam is indicated for the treatment of male pattern baldness.

DOSE AND METHOD OF ADMINISTRATION

Men aged 18-49:
Hair and scalp should be thoroughly dry prior to topical application of Minoxidil 5% w/w cutaneous foam. A dose of 1 g (equivalent to the volume of one capful) Minoxidil 5% w/w cutaneous foam should be applied to the total affected areas of the scalp twice daily. The total daily dosage should not exceed 2 g.

Hold can upside down and press nozzle to dispense foam onto the hand. Spread with fingertips over entire bald area. Hands should be washed thoroughly after application.

It may take twice-daily applications for 8 weeks or more before evidence of hair growth can be expected. Users should discontinue treatment if there is no improvement seen after 16 weeks.
If hair regrowth occurs, twice daily applications of Minoxidil 5% w/w cutaneous foam are necessary for continued hair growth.
Reported clinical Trials have not investigated the efficacy of Minoxidil 5% w/w cutaneous foam beyond 16 weeks.

Children
Not recommended. The safety and effectiveness of Minoxidil 5% w/w cutaneous foam in users aged under 18 years has not been established.

USE IN SPECIAL POPULATIONS
Systemically absorbed minoxidil is secreted in human milk.
There are no adequate and well-controlled studies in pregnant women.
Animal studies have shown a risk to the foetus at exposure levels that are very high compared to those intended for human exposure. A low, albeit remote, risk of foetal harm is possible in humans.
Minoxidil 5% w/w cutaneous foam should not be used during pregnancy or lactation.

CONTRAINDICATIONS
Minoxidil 5% w/w cutaneous foam is contraindicated:
- In users with a history of sensitivity to Minoxidil or any of the other ingredients
- In users suffer from high blood pressure, whether treated or not
- In users with any scalp abnormality (an itchy inflammatory skin condition) or sunburn
- In users with a shaved scalp
- If users are using other medicines or occlusive dressings, such as plasters or air tight dressings,
- on your scalp.
- If user are pregnant or breast feeding
- If user are younger than 18 years or older than 65 years.

WARNINGS AND PRECAUTIONS
- Before using Minoxidil 5% w/w cutaneous foam, the user should determine that the scalp is normal and healthy
- Minoxidil is not indicated when there is no family history of hair loss, hair loss is sudden and/or patchy, hair loss is due to childbirth, or the reason for hair loss is unknown.
- The patient should stop using Minoxidil 5% w/w cutaneous foam and see a doctor if hypotension is detected or if the patient is experiencing chest pain, rapid heartbeat, faintness or dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness.
- Patients with known cardiovascular disease or cardiac arrhythmia should contact a physician before using Minoxidil 5% w/w cutaneous foam.
- Minoxidil 5% w/w cutaneous foam is for external use only. Do not apply to areas of the body other than the scalp.
- Hands should be washed thoroughly after applying the foam.
- As reported, some patients have experienced changes in hair colour and/or texture with Minoxidil 5% w/w cutaneous foam use.

Some consumers reported increased hair shedding upon initiation of therapy with Minoxidil 5% w/w cutaneous foam. This is most likely due to minoxidil's action of shifting hairs from the resting telogen phase to the growing anagen phase (old hairs fall out as new hairs grow in their place). This temporary increase in hair shedding generally occurs two to six weeks after beginning treatment and subsides within a couple of weeks. If shedding persists (> 2 weeks), users should stop using Minoxidil 5% w/w cutaneous foam and consult their doctor.
Users should be aware that, whilst extensive use of Minoxidil 5% w/w cutaneous foam has not revealed evidence that sufficient minoxidil is absorbed to have systemic effects, greater absorption because of misuse, individual variability, unusual sensitivity or decreased integrity of the epidermal barrier caused by inflammation or disease processes in the skin (eg. excoriations of the scalp, or scalp psoriasis) could lead, at least theoretically, to systemic effects.

DRUG INTERACTIONS
Topical drugs, such as tretinoin or dithranol, which alter the stratum corneum barrier, could result in increased absorption of minoxidil if applied concurrently. Although it has not been demonstrated clinically, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.
Betamethasone diproprionate increases local tissue concentrations of minoxidil and decreases systemic minoxidil absorption.

UNDESIRABLE EFFECTS
For the assessment of undesirable effects the following frequencies apply:
Very common (≥1/10); common (≥1/100,<1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).
The following adverse events were associated with the use of minoxidil solution (2% and 5% combined) in males and females, at an incidence greater than 1 %, and greater than placebo in seven placebo-controlled reported clinical trials.

Very Common:
Neurological: headache

Common:
Respiratory: dyspnoea
Dermatological: pruritus, hypertrichosis, acneform rash, dermatitis, inflammatory skin disorder
Musculoskeletal: musculoskeletal pain

Metabolic/Nutritional: peripheral oedema
Psychiatric: depression
Miscellaneous: pain

Clinical Trial with Minoxidil Foam
The following adverse events were associated with the use of 5% minoxidil foam in males, at an incidence greater than 1 %, and greater than placebo in one placebo-controlled reported clinical trial.

Common:
Body as a Whole: headache
Skin: pruritus, rash
Cardiovascular: hypertension

Post Marketing Experience - Minoxidil Solution
The following additional adverse events which have been observed with the application of topical minoxidil solutions during post-marketing use might also be relevant for topical minoxidil foam: irritation at the application site, dry skin, skin exfoliation, temporary hair loss, application site erythema, contact dermatitis or hypotension.
Users should stop using minoxidil 5% w/w cutaneous foam if they experience chest-pain, tachycardia, faintness, dizziness, sudden unexplained weight gain, swollen hands or feet or persistent redness or irritation of the scalp.

OVERDOSE
Increased systemic absorption of minoxidil may potentially occur if higher-than-recommended doses of minoxidil 5% w/w cutaneous foam are applied to larger surface areas of the body or areas other than the scalp.
Because of the concentration of minoxidil in 5% w/w cutaneous foam, accidental ingestion has the potential of producing systemic effects related to the pharmacological action of the drug (2 g of minoxidil 5% w/w cutaneous foam contains 100 mg minoxidil; the maximum recommended adult dose for oral minoxidil administration in the treatment of hypertension). Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects associated with sodium and water retention, and tachycardia, hypotension and dizziness can also occur. Fluid retention can be managed with appropriate diuretic therapy. Clinically significant tachycardia can be controlled by administration of a beta-adrenergic blocking agent.

Treatment
Treatment of minoxidil overdosage should be symptomatic and supportive.

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: Other dermatologicals, ATC code: D11AX.

Minoxidil stimulates hair growth in persons with early and moderate stages of hereditary hair loss (alopecia androgenetica). This hair loss appears in men as a receding hairline and balding in the vertex area. The exact mechanism of action of minoxidil for topical treatment of alopecia is not fully understood, but minoxidil can reverse the hair loss process of androgenetic alopecia by the following means:

- increasing the diameter of the hair shaft
- stimulating anagen growth
- prolonging the anagen phase
- stimulating anagen recovery from the telegen phase

As a peripheral vasodilator minoxidil enhances microcirculation to hair follicles. The Vascular Endothelial Growth Factor (VEGF) is stimulated by minoxidil and VEGF is presumably responsible for the increased capillary fenestration, indicative of a high metabolic activity, observed during the anagen phase.

Pharmacokinetic properties

There is some evidence from reported in vitro studies that minoxidil reversibly binds to human plasma proteins. However, since only 1 – 2% of topically applied minoxidil is absorbed, the extent of plasma protein binding occurring in vivo after topical application would be clinically insignificant. The volume of distribution of minoxidil after intravenous administration has been estimated at 70 litres.

Approximately 60% minoxidil absorbed after topical application is metabolised to minoxidil glucuronide, primarily in the liver. Minoxidil and its metabolites are excreted almost entirely in the urine, with a very minor degree of elimination via the faeces. Following cessation of dosing, approximately 95% of topically applied minoxidil will be eliminated within four days.

EXPIRY DATE

Do not use later than the date of expiry

PACKAGING INFORMATION

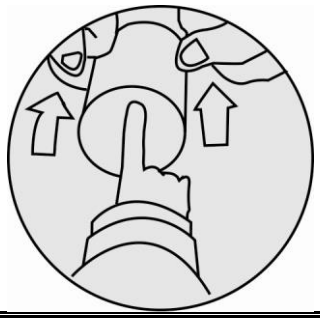
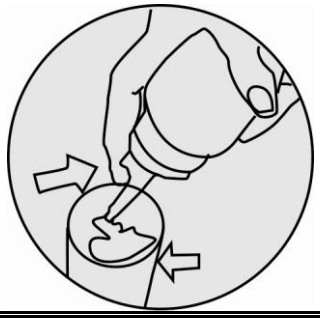
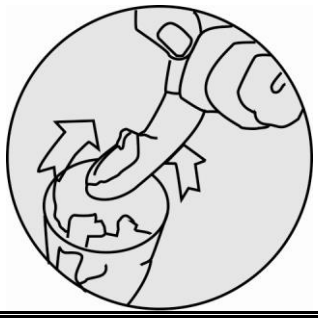
Minoxidil Topical Foam is available as One 60 g (2.11 oz) Can

STORAGE AND HANDLING INSTRUCTIONS

- Store below 25°C in a cool dry place. Do not refrigerate. Do not expose to high temperatures. Protect from light.
- Do not take out the foam when can is in the upright position as this will lead to loss of propellants. The foam should not be mixed with any hair oil or hair dye.
- The contents are under pressure. The container should not be punctured or incinerated. The product is extremely flammable and exposure of the container and contents to naked flames should be avoided during use, storage and disposal. Do not expose to temperatures above 50°C.
- Any unused product or waste material should be disposed of in accordance with the local requirements.
- Flammble, avoid flame or smoking during and immediately following Application.
- Contents under pressure Do not puncture or incinerate manner or expose to heat.
- For External use only
- Dose: As directed by the Physician.
- Keep all medicines out of reach of children.
- Shake well before every use

DIRECTIONS FOR USE

Your hair and scalp should be dry before applying Hairjoy foam.

	1. Remove the cap.
	2. Identify the seal. Push back the nozzle gently to break the seal. The product is now ready to use.
	3. Shake the can before use. Hold the can upside down and press the nozzle to dispense a capful of Minoxidil foam. **<u>Caution: Do not take out the foam when can is in the upright position as this will lead to loss of propellant.</u>**
	4. Use your finger tip to take the foam.
	5. Within the hair thinning area, part the hair and gently massage the foam onto the scalp.

Manufactured by:
Torrent Pharmaceuticals Ltd.
Indrad-382721,Dist-Mehsana,INDIA.
At:B-16, MIDC,WALUJ,
AURANGABAD-431 136, INDIA

Details of permission or licence number with date
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MARKETED BY


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IN/Hairjoy foam 5%w/w/MAY-21/03/PI