**TUGAIN Solution (Minoxidil)**

### Composition

**TUGAIN Solution 2**
- Minoxidil ......................... 2% w/v
- Also contains:
  - Absolute alcohol ............... 63% v/v

**TUGAIN Solution 5**
- Minoxidil ......................... 5% w/v
- Also contains:
  - Absolute alcohol ............... 30% v/v

**TUGAIN Solution 10**
- Minoxidil ......................... 10% w/v
- Also contains:
  - Absolute alcohol ............... 40% v/v

### Dosage Form

Solution

### Pharmacology

#### Pharmacodynamics

Minoxidil stimulates hair growth in persons with early and moderate stages of androgenic alopecia. It is not intended for frontal baldness or a receding hairline.

The mechanism by which minoxidil stimulates hair growth is not established, but possible mechanisms of action of minoxidil may include the following:

- K+ATP-mediated stimulation of hair follicular cells by one of its sulphated active metabolites.
- Stimulation and prolongation of the anagen phase of hair and increase in the follicular size, thereby preventing premature entry into the telogen phase.
- Improvement in local microcirculation through its vasodilatory effect. Minoxidil stimulates VEGF (vascular endothelial growth factor) which is responsible for increased capillary fenestration, indicative of high metabolic activity, observed in anagen phase.
- Increasing diameter of the hair shaft
- Stimulating anagen recovery from the telogen phase.

All people may not be responsive to topical minoxidil treatment. The amount of hair regrowth differs from person to person. Although data suggest that those users who have been balding for a shorter period or who have a smaller area
of baldness on the vertex are more likely to respond to topical minoxidil, individual responses cannot be predicted. It is unlikely anyone will be able to grow back all of his or her hair.

### Pharmacokinetics

Following topical application of minoxidil 2% Solution, an average of about 1.4% (range: from 0.3% to 4.5%) of the total applied dose is absorbed from the normal intact scalp, but this reflects poor absorption of topical minoxidil. Topical minoxidil absorption is increased by increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum.

Results of the extensive pharmacokinetic studies indicate that the three major factors by which topical minoxidil absorption are increased by are: increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum.

In a study in males, the minoxidil serum concentration time curve (AUC) for the 2% solution averaged 7.54 ng·h/ml compared to a mean AUC of 35.1 ng·h/ml for the 2.5 mg oral formulation. The mean peak plasma concentration ($C_{\text{max}}$) for the topical solution was 1.25 ng/ml, compared to 18.5 ng/ml following the 2.5 mg oral dose.

In another study the systemic absorption of minoxidil from a 5% solution formulation has been estimated in subjects with androgenetic alopecia, which included 5% topical foam as a comparator. This demonstrated that in men, the systemic absorption of minoxidil from twice daily application of 5% minoxidil solution was about twice that, as observed with 5% minoxidil foam. The mean steady state AUC (0-12 hr) and $C_{\text{max}}$ for 5% minoxidil foam, 8.81 ng·hr/mL and 1.11 ng/mL, respectively, were both approximately 50 % of AUC (0-12 hr) and $C_{\text{max}}$ of the 5% solution, 18.71 ng·hr/mL and 2.13 ng/mL, respectively. The time to maximum minoxidil concentration (Tmax) for the 5% solution, 5.79 hr, was similar to Tmax for the 5% foam, 5.42 hr.

There is some evidence from *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.

Serum Minoxidil levels and systemic effects resulting from administration of Minoxidil 2% Solution are governed by the drug's absorption rate through the skin. 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.

### Indications

TUGAIN Solution 2 is indicated for the treatment of androgenic alopecia in men with male pattern baldness and women with female pattern baldness.

TUGAIN Solution 5/10 is indicated for the treatment of androgenic alopecia only in men.

### Dosage And Administration

Minoxidil topical solution is for external use only. It should be used only as directed.

**Dropper applicator**

Remove the large outer cap on the TUGAIN Solution bottle, and then remove the inner cap. Insert the dropper applicator into the bottle and squeeze the rubber bulb. Release the bulb, allowing TUGAIN
Solution to fill up to the 1 mL mark.
Gradually pour the solution from the dropper onto the centre of the area where the hair is thin.
Spread it evenly with your fingertips. To prevent the solution from running off the scalp, apply a small amount at a time.

*Spray applicator (Works on a large area of baldness)*
Remove the large outer cap on the TUGAIN Solution bottle and then remove the inner cap.
Replace the inner cap with the spray applicator. Screw on the spray applicator firmly.
Aim the applicator towards the centre of the hair loss area (4-6 cm away from the scalp) and press the pump once to release 0.2 ml of the solution.
Spread the solution with the fingertips to cover all of the hair loss area. Repeat for a total of five times, including the first application (1 ml).

Minoxidil topical solution should be applied when the hair and scalp are clean and dry. Apply 1 ml of minoxidil topical solution twice daily at 12-hour intervals to the scalp, beginning at the centre of the affected area and spreading the solution out to cover the entire affected area. The total daily application dose should not exceed 2 ml.
For best results, minoxidil topical solution should be allowed to remain on the scalp for about 4 hours before washing. The night-time application should be done 2-4 hours before going to bed to allow the solution to dry out.
Minoxidil topical solution should not be massaged into the scalp, but applied lightly. A hair dryer should not be used to speed up the drying of the solution as it may decrease the effectiveness. Minoxidil topical solution should not be mixed with any hair oil.
The drug should not be used more than two times a day, or be taken orally or applied to any other part of the body to avoid the risk of adverse effects and unwanted hair growth.
More frequent use or longer application time have no effect on the hair growth. In case of missing any daily applications of minoxidil topical solution, the patient should continue with the next application.
Hands should be washed immediately if minoxidil topical solution is applied with the fingertips.
Clinical experience with minoxidil indicates that twice-daily applications for 4 months or more may be required before there is evidence of hair growth. To arrest hair fall, minoxidil topical solution should be used for not less than 45 days. Treatment should be discontinued if there is no improvement after one year.

**Contraindications**

Patients with a history of hypersensitivity to any of the ingredients of the product.
Patients with cardiac abnormalities.
Children below 18 years of age, pregnant women and nursing mothers.
Patients in whom the reason for hair loss is unknown.
Patients using occlusive dressings or other medicines on the scalp.
On a shaved scalp, or if there is no family history of hair loss; there is sudden and/or patchy hair loss.
Patients with red, inflamed infection, or irritated or painful scalp (including psoriasis and sunburn).
Patients with hypovolaemic states (e.g., co-treatment with diuretics, dehydration, etc.)
Patients with treated or untreated hypertension

**Warnings And Precautions**

TUGAIN Solution is clear and colourless; however, its colour may vary and, occasionally, it may have a yellow appearance. The colour of the solution will not affect its effectiveness, nor should it cause staining of clothes or skin. The solution will have no color when it has dried on the scalp.
Minoxidil solution is more likely to cause scalp irritation. If scalp irritation continues or worsen, use of TUGAIN Solution should be stopped.

Use of TUGAIN Solution should be stopped if the patient develops chest pain, rapid heartbeat, faintness or dizziness, sudden and unexplained weight gain, swollen hands or feet or persistent redness or irritation of the scalp or other unexpected new symptoms occur.

TUGAIN Solution contains alcohol, which will cause burning and irritation of the eyes. In case of accidental contact with sensitive surfaces (such as eyes, abraded skin and mucous membranes), the area should be rinsed with large amounts of cool tap water.

If needed, the scalp can be washed with a mild shampoo before applying TUGAIN Solution. Hair sprays or hair styling aids may be used on the hair while using TUGAIN Solution, but for best results, it should be allowed to penetrate into the scalp before using any styling products.

Before colouring or perming hair or using hair relaxers, the following precautions are recommended:

- To avoid possible scalp irritation, TUGAIN Solution should be washed off the hair and scalp thoroughly.
- For best results, application of TUGAIN Solution should be avoided.
- Do not use TUGAIN Solution for 24 hours after any perm or colour treatment to make sure that any chemicals used have not irritated the scalp. If no irritation occurs, continue use of minoxidil topical solution.

### Drug Interactions

TUGAIN Solution should not be used along with other topical agents known to alter the stratum corneum barrier such as corticosteroids, tretinoin, dithranol or petrolatum, as they could result in enhanced absorption of minoxidil. Although there is no clinical evidence, there exists the theoretical possibility of absorbed minoxidil potentiating orthostatic hypotension caused by peripheral vasodilators.

Guanethidine has been reported to interact with oral formulations of minoxidil resulting in rapid and pronounced lowering of blood pressure. There is a theoretical possibility that topical minoxidil may also interact with guanethidine.

### Pregnancy

TUGAIN Solution is contraindicated in pregnant women.

### Lactation

TUGAIN Solution is contraindicated in nursing mothers.

### Paediatric Use

TUGAIN Solution is not recommended for use in children. The safety and efficacy of minoxidil topical solution in children below 18 years of age have not been established.

### Geriatric Use

TUGAIN Solution is not recommended for use in elderly persons (aged above 65 years) as the safety and efficacy of minoxidil topical solution in this age group have not been established.

### Undesirable Effects

In placebo-controlled trials, the overall frequency of medical events in females in all body system categories was approximately five times that of males.

Data from 7 placebo controlled trials are available with a population of 1,197 males and females treated with topical minoxidil solution (2% and 5% combined) where adverse events were assessed. Additionally, adverse events reported in post-marketing and and two placebocontrolled randomized clinical trials in adults evaluating a 5% foam formulation are
The frequency of adverse reactions to topical minoxidil is defined using the following convention:

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).

**Very common**

- Headache

**Common**

- Hypersensitivity reactions (including: face oedema, generalised erythema, pruritus generalised, swelling face, and throat tightness)
- Chest pain
- Hypertrichosis (unwanted non-scalp hair including facial hair growth in women)
- Pruritus (including rash pruritic, generalized and eye pruritus)
- Rash (including pustular, papular, generalised, vestibular and macular rash)
- Dermatitis (including contact, allergic, atopic and seborrhoeic dermatitis)
- Weight increased

**Uncommon**

- Dizziness
- Palpitations
- Dyspnoea
- Nausea
- Dry skin
- Skin exfoliation (including exfoliative rash and dermatitis exfoliative)
- Acne (acneiform rash)
- Temporary hair loss, changes in hair texture and hair colour
- Application site reactions (These sometimes involve nearby structures like the ears and face and typically consist of pruritus, irritation, pain, rash, oedema, dry skin, erythema and rash erythematous but can sometimes be more severe and include exfoliation, dermatitis, blistering, bleeding and ulceration)

**Rare**

- Changes in hair texture

**Not known**

- Angioedema (including lip oedema, lip swelling, oedema mouth, oropharyngeal swelling, pharyngeal oedema, swollen tongue and tongue oedema)
- Depressed mood
- Eye irritation
- Tachycardia
- Hypotension
- Vomiting
- Dry skin
- Skin exfoliation (including exfoliative rash and dermatitis exfoliative)
- Acne (acneiform rash)
- Temporary hair loss
- Changes in hair colour
- Application site reactions (These sometimes involve nearby structures like the ears and face and typically consist of pruritus, irritation, pain, rash, oedema, dry skin, erythema and rash erythematous but can sometimes
be more severe and include exfoliation, dermatitis, blistering, bleeding and ulceration)

Users should stop using topical minoxidil solution if they experience chest pain, tachycardia, faintness, dizziness, sudden unexplained weight gain, swollen hands or feet, or persistent redness or irritation of the scalp.

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024. By reporting side effects you can help provide more information on the safety of this product.

**Overdosage**

Overdosage with minoxidil results from systemic absorption, which may occur if minoxidil topical solution is applied more frequently than indicated or if it is applied to large surface areas of the body or areas other than the scalp. There is no data of minoxidil overdosage resulting from topical administration.

Signs and symptoms of minoxidil overdosage because of accidental ingestion or deliberate overdose would primarily be cardiovascular effects associated with sodium and water retention, and tachycardia.

Treatment should include diuretic therapy to manage fluid retention and beta-adrenergic blocking drugs for controlling clinically significant tachycardia. Minoxidil and its metabolites are haemodialysable.

**Shelf-Life**

TUGAIN Solution 2.............18 months
TUGAIN Solution 5.............18 months
TUGAIN Solution 10............18 months

**Storage And Handling Instructions**

Store in a cool place. Protect from light.

**Packaging Information**

TUGAIN Solution 2: Bottle of 60 ml
TUGAIN Solution 5: Bottle of 60 ml
TUGAIN Solution 10: Bottle of 60 ml

**How To Use Your Tugain Solution**

How to Use the Applicators?

Dropper applicator
Spray applicator

*Dropper applicator*

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Spray applicator (Works on a large area of baldness)

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Aim the applicator towards the centre of the hair loss area (4-6 cm away from the scalp) and press the pump once to release 0.2 ml of the solution.

Spread the solution with the fingertips to cover all of the hair loss area. Repeat for a total of five times, including the first application (1 ml).

For TUGAIN Solution to work best, you should allow it to stay on the scalp at least 4 hours before washing it off.

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