TUGAIN Solution (Minoxidil)

### Composition

<table>
<thead>
<tr>
<th>TUGAIN Solution 2</th>
<th>Minoxidil</th>
<th>2% w/v</th>
</tr>
</thead>
<tbody>
<tr>
<td>Also contains:</td>
<td>Absolute alcohol</td>
<td>63% v/v</td>
</tr>
<tr>
<td>TUGAIN Solution 5</td>
<td>Minoxidil</td>
<td>5% w/v</td>
</tr>
<tr>
<td>Also contains:</td>
<td>Absolute alcohol</td>
<td>30% v/v</td>
</tr>
<tr>
<td>TUGAIN Solution 10</td>
<td>Minoxidil</td>
<td>10% w/v</td>
</tr>
<tr>
<td>Also contains:</td>
<td>Absolute alcohol</td>
<td>40% v/v</td>
</tr>
</tbody>
</table>

### Dosage Form

Solution

### Pharmacology

#### Pharmacodynamics

Minoxidil topical solution is for patients with pattern baldness. 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:

1. K+ATP-mediated stimulation of hair follicular cells by one of its sulphated active metabolites.
2. Prolongation of the anagen phase of hair and increase in the follicular size, thereby preventing premature entry into the telogen phase.
3. Improvement in local microcirculation.
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 minoxidil topical solution, 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_{max}) for the topical solution was 1.25 ng/ml, compared to 18.5 ng/ml following the 2.5 mg oral dose.

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.

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.

### 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.)

### 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.
**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.

### 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 are included.

The frequency of adverse reactions to topical minoxidil solution 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).

### Common

- Headache
- Hypertrichosis (unwanted non-scalp hair including facial hair growth in women)
- Pruritus (including rash pruritic and application site, generalized and eye pruritus)

### Uncommon

- Hypotension
- Temporary hair loss, changes in hair texture and hair colour
- Skin exfoliation (including application site, exfoliative rash and dermatitis exfoliative)
- Rash (including application site, pustular, papular, generalized vestibular and macular rash)
- Acne (acne form rash)
- Dermatitis (including contact, application site, allergic, atopic and seborrhoeic dermatitis)
- Dry skin (including application site dryness)
- Oedema peripheral, Application site irritation (including skin irritation), application site erythema (including erythema and rash erythematous)

### Rare

- Palpitations
- Heart Rate Increased
- Chest Pain

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

### 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**

2 years

**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**
Your hair and scalp should be dry before applying **TUGAIN Solution**

Open the cap.

Remove the stopper.

Squeeze the bottle until the solution comes up close to the rim. Then release it.

Automatically, 1 ml of the solution will collect in the neck of the bottle. Remove it by using the dropper.

Pour the solution from the dropper onto the centre of the area of the scalp where the hair is thin. Spread it evenly with your fingertips.

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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**TUGAIN Solution**

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