TUGAIN Gel (Minoxidil)

Composition

TUGAIN Gel 5
Minoxidil IP ......................... 5% w/w
Also contains:
Absolute alcohol ................. 30% v/w

Dosage Form

Gel

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: increasing the dose applied, increasing the frequency of dosing and decreasing the barrier function of the stratum corneum.

In a 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 ($T_{\text{max}}$) for the 5% solution, 5.79 hr, was similar to $T_{\text{max}}$ 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 Gel 5 is indicated for the treatment of androgenic alopecia only in men.

#### Dosage and Administration

TUGAIN Gel is for external use only. It should be used only as directed. TUGAIN Gel should be applied when the hair and scalp are clean and dry. One actuation from the gel bottle provides 1 gm of minoxidil topical gel. Apply 1 gm of TUGAIN Gel twice daily at 12-hour intervals to the scalp, beginning at the centre of the affected area and spreading the gel out to cover the entire affected area. The total daily application dose should not exceed 2 gm.

For best results, TUGAIN GEL 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 gel to dry out.

TUGAIN GEL should not be massaged into the scalp, but applied lightly. A hair dryer should not be used to speed up the drying of the gel as it may decrease the effectiveness. TUGAIN Gel should not be mixed with any hair oil.

The drug should not be used more frequently 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 TUGAIN Gel, the patient should continue with the next dose.

Hands should be washed immediately if TUGAIN Gel 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, TUGAIN Gel should be used for not less than 45 days. Treatment should be discontinued if there is no improvement after one year. Anecdotal reports indicate that re-grown hair may disappear three to four months after stopping TUGAIN Gel application and the balding process will continue.

### Contraindications
TUGAIN Gel is contraindicated in the following conditions:

- 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**

### General

TUGAIN Gel is clear and colourless; however, its colour may vary and, occasionally, it may have a yellow appearance. The colour of the gel will not affect its effectiveness, nor should it cause staining of clothes or skin. The gel will have no colour when it has dried on the scalp.

Minoxidil gel is likely to cause scalp irritation. If scalp irritation continues or worsen, use of TUGAIN Gel should be stopped.

Use of TUGAIN Gel 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.

Patients with known cardiovascular disease or cardiac arrhythmia should contact a physician before using TUGAIN Gel. Some patients have experienced changes in hair colour and/or texture with use of minoxidil. Using more than the recommended dose or more often will not improve results.

Unwanted hair growth may be caused by the transfer of the product to areas other than the scalp. Hands should be washed thoroughly after applying the solution.

Some patients reported increased hair shedding upon initiation of therapy with TUGAIN Gel. 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 TUGAIN Gel and consult their doctor.

Users should be aware that, whilst extensive use of TUGAIN Gel 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 (e.g. excoriations of the scalp, or scalp psoriasis) could lead, at least theoretically, to systemic effects.

Accidental ingestion may cause serious cardiac adverse events. Therefore this product has to be kept out of the reach of children.

TUGAIN Gel contains an alcohol base, 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 Gel. Hair sprays or hair styling aids may be used on the hair while using minoxidil topical gel, 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 Gel should be washed off the hair and scalp thoroughly.
For best results, application of TUGAIN Gel should be avoided.
Do not use minoxidil topical gel 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 TUGAIN Gel.

### Drug Interactions

TUGAIN Gel should not be used concomitantly with other medications applied to scalp Topical corticosteroids, tretinoin,
dithranol or petrolatum which alter the stratum corneum barrier, could result in enhanced absorption of minoxidil if
applied concurrently. 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 Gel is contraindicated in pregnant women.
There are no adequate and well-controlled studies in pregnant women. Studies in animals have shown a risk to the
foetus at exposure levels that are very high compared to those intended for human exposure. There is potentially a risk
of foetal harm in humans.

### Lactation

TUGAIN Gel is contraindicated in nursing mothers.
Systemically absorbed minoxidil is secreted in human milk. The effect of minoxidil on newborns/infants is unknown.

### Paediatric Use

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

### Geriatric Use

TUGAIN Gel is not recommended for use in elderly persons (aged above 65 years) as the safety and efficacy of topical
minoxidil 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 two placebocontrolled randomized clinical trials in adults evaluating a 5% foam formulation are
included.
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).
ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or
epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as
<table>
<thead>
<tr>
<th>Body System (SOC)</th>
<th>Frequency</th>
<th>Adverse Drug Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immune System Disorders</strong></td>
<td>Common</td>
<td>Hypersensitivity reactions (including face oedema, generalised erythema, pruritus</td>
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<tr>
<td></td>
<td></td>
<td>generalised, swelling face, and throat tightness)</td>
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<tr>
<td></td>
<td>Not known</td>
<td>Angioedema (including lip oedema, lip swelling, oedema mouth, oropharyngeal swelling,</td>
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<td></td>
<td></td>
<td>pharyngeal oedema, swollen tongue and tongue oedema)</td>
</tr>
<tr>
<td><strong>Psychiatric Disorders</strong></td>
<td>Not known</td>
<td>Depressed mood</td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td>Very common</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Uncommon</td>
<td>Dizziness</td>
</tr>
<tr>
<td><strong>Eye disorders</strong></td>
<td>Not known</td>
<td>Eye irritation</td>
</tr>
<tr>
<td><strong>Cardiac disorders</strong></td>
<td>Common</td>
<td>Chest pain</td>
</tr>
<tr>
<td></td>
<td>Uncommon</td>
<td>Palpitations</td>
</tr>
<tr>
<td></td>
<td>Not known</td>
<td>Heart rate increased</td>
</tr>
<tr>
<td><strong>Vascular disorders</strong></td>
<td>Not known</td>
<td>Hypotension</td>
</tr>
<tr>
<td>**Respiratory, thoracic and mediastinal</td>
<td>Uncommon</td>
<td>Dyspnoea</td>
</tr>
<tr>
<td>disorders**</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td>Uncommon</td>
<td>Nausea</td>
</tr>
<tr>
<td>Condition</td>
<td>Frequency</td>
<td>Description</td>
</tr>
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<td>-----------</td>
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</tr>
<tr>
<td>Not known</td>
<td>Vomiting</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Common</td>
<td>Hypertrichosis (unwanted non-scalp hair including facial hair growth in women) Pruritus (including rash pruritic) Rash (including pustular, papular, generalised, vestibular and macular rash) Dermatitis (including contact, allergic, atopic and seborrheic dermatitis)</td>
</tr>
<tr>
<td>Rare</td>
<td>Changes in hair texture</td>
<td></td>
</tr>
<tr>
<td>Not Known</td>
<td>Dry skin</td>
<td>Skin exfoliation (including exfoliative rash and dermatitis exfoliative) Acne (acneiform rash) Temporary hair loss Changes and hair colour</td>
</tr>
<tr>
<td>General disorders and administration Common site conditions</td>
<td>Common</td>
<td>Oedema peripheral</td>
</tr>
<tr>
<td>Not known</td>
<td>Application site reaction (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)</td>
<td></td>
</tr>
<tr>
<td>Investigations</td>
<td>Common</td>
<td>Weight increased</td>
</tr>
</tbody>
</table>

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**

Increased systemic absorption of minoxidil may potentially occur if higher- than-recommended doses of TUGAIN Gel are
applied to larger surface areas of the body or areas other than the scalp. Signs and symptoms of minoxidil overdosage would primarily be cardiovascular effects associated with sodium and water retention. Tachycardia, hypotension, dizziness and lethargy can also occur.

### Treatment

Treatment of minoxidil overdosage should be symptomatic and supportive. Treatment should include diuretic therapy to manage fluid retention and beta-adrenergic-blocking drugs for controlling clinically significant tachycardia.

### Shelf-Life

2 years

### Storage And Handling Instructions

Store in a cool place.
Protect from light.

### Packaging Information

TUGAIN Gel 5: Bottle containing 60 gm of gel

### How To Use Your Tugain Gel

Your hair and scalp should be dry before applying TUGAIN Gel
Open the cap.
Firmly press down the pump once to release the gel onto your palm.
Take the gel onto your fingertip.
Apply the gel over the scalp, where the hair is thin. Spread it evenly.
After use, recap the bottle tightly
For TUGAIN Gel to work best, you should allow it to stay on the scalp for at least 4 hours before washing it off.

Last updated: Oct 2018
Last reviewed: Oct 2018

TUGAIN Gel

Source URL: https://ciplamed.com/content/tugain-gel