

TUGAIN MEN Solution (Minoxidil 5% + Finasteride 0.1%)

What is TUGAIN MEN Solution?

TUGAIN MEN Solution is a solution containing a combination of minoxidil 5% and finasteride 0.1%, which helps to regrow hair. It is to be used only on the scalp.

Who can use TUGAIN MEN Solution?

TUGAIN MEN Solution is indicated for the treatMENT of androgenetic alopecia **only in MEN in the age group of 18 to 60 years**. It should not be used by woMEN.

WoMEN should not handle **TUGAIN MEN Solution** when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male foetus.

How does minoxidil and finasteride help regrow hair?

When applied topically, minoxidil topical solution has been shown to stimulate hair growth in individuals with androgenetic alopecia. Although the exact mechanism of action of minoxidil is not established, the 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 vascular endothelial growth factor (VEGF), which is responsible for increased capillary fenestration, indicative of high metabolic activity, observed in the anagen phase.
- Increasing the diameter of the hair shaft.
- Stimulating anagen recovery from the telogen phase.

In MEN with androgenetic alopecia, the balding scalp contains miniaturized hair follicles and increased amounts of dihydrotestosterone (DHT) compared with hairy scalp. Finasteride, is a specific inhibitor of type II 5 alpha-reductase, an intracellular enzyme that converts androgenic testosterone into DHT, the key factor in androgenetic alopecia. Application of finasteride decreases scalp DHT concentration in MEN, which may contribute to the treatMENT effect.

What are the pharmacokinetic properties of minoxidil and finasteride?

Following topical application of minoxidil topical solution, minoxidil is poorly absorbed from the normal intact skin, with an average of 1.4% (range, 0.3 to 4.5%) of the total applied dose reaching the systemic circulation. The effects of concomitant dermal diseases and occlusion on absorption are unknown. Serum minoxidil levels resulting from topical administration are governed by the drug's

percutaneous absorption rate; increases in surface area of application do not result in proportionate increase in the serum minoxidil level. Steady state is achieved by the end of the third dosing interval (36 hours) when the drug is administered twice daily. Approximately 95% of the systemically absorbed minoxidil from topical dosing is eliminated within 4 days. The metabolic biotransformation of minoxidil absorbed following topical application has not been fully determined.

Known metabolites exert much less pharmacologic effect than minoxidil itself and all are excreted principally in the urine. Minoxidil does not bind to plasma proteins; its renal clearance corresponds to glomerular filtration rate and it does not cross the blood-brain barrier. Minoxidil and its metabolites are haemodialysable, although this does not rapidly reverse its pharmacologic effect.

The pharmacokinetics of finasteride following topical administration has not been evaluated systemically. However, it is expected that it will be poorly absorbed from normal intact skin, with a minimal of the total applied dose reaching the systemic circulation.

How effective is minoxidil in regrowing hair?

The amount of hair regrowth is different for each person. Not everyone will respond to minoxidil. You may respond better if it has just been a short period since you have been losing your hair, or are experiencing just a little initial hair loss. Your doctor can best decide whether you are likely to respond to treatment with **TUGAIN MEN Solution**.

How soon can you expect results from using TUGAIN MEN Solution?

Since normal hair usually grows only about ½ inch to 1 inch per month, hair growth with **TUGAIN MEN Solution** will also take time. You will need to continuously use **TUGAIN MEN Solution** two times a day for at least 4 to 6 months before you notice hair regrowth. Onset and degree may be variable among patients.

Do note:

- During the first few weeks of use, you may find a temporary increase in hair loss. Don't worry, this is a good sign because it shows that a new hair cycle is beginning and is just part of the process by which **TUGAIN MEN Solution** regrows hair. But, if this hair loss continues beyond 6 weeks, talk to your doctor.

If TUGAIN MEN Solution is working, what will the regrown hair look like?

After 4 to 6 months when you check for results, always look for hair that is fine and very light-coloured because, at first, this is how the regrowing hair will appear. This is a positive sign and means that **TUGAIN MEN Solution** is actually stimulating regrowth. With further use, the regrown hair should be the same colour and thickness as the other hair on your scalp.

How many times a day should you use TUGAIN MEN Solution?

You have to apply **TUGAIN MEN Solution** (1 ml dose) twice daily once in the morning and once at

night. At night, allow the solution to dry out completely before going to bed.

How and when should TUGAIN MEN Solution be used?

- **TUGAIN MEN Solution** should be applied to the hair and scalp when they are completely dry. Use the dosage suggested by the doctor.
- Apply 1 ml of **TUGAIN MEN Solution** twice daily, at an interval of 12 hours, to the hair loss area of the scalp.
- Massage the solution gently into the scalp and wash your hands after application.
- The total daily application dose should not exceed 2 ml.
- **TUGAIN MEN Solution** should be applied when the hair and scalp are clean and dry.
- For best results, **TUGAIN MEN Solution** should be allowed to remain on the scalp for about 4 hours before washing. The nighttime application should be done 2 to 4 hours before going to bed to allow the solution to dry out.

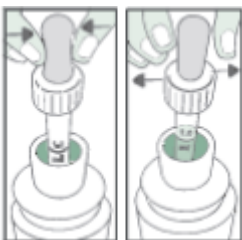
What is the procedure to apply TUGAIN MEN Solution using the dropper applicator?

Dropper

1. Remove the large outer cap on the **TUGAIN MEN Solution** bottle, and then remove the inner cap.



1. Insert the dropper applicator into the bottle and squeeze the rubber bulb. Release the bulb, allowing **TUGAIN MEN Solution** to fill up to the 1 ml mark.



1. Gradually pour the solution from the dropper onto the centre of the area where the hair is thin.



1. Spread it evenly with your fingertips. To prevent the solution from running off the scalp, apply a

small amount at a time.



What is the procedure to apply TUGAIN MEN Solution using the spray applicator?

Spray (works on a large area of baldness)

1. Remove the large outer cap on the **TUGAIN MEN Solution** bottle, and then remove the inner cap.



1. Replace the inner cap with the spray applicator. Screw on the spray applicator firmly.



1. 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.



1. Spread it evenly with fingertips to cover all of the hair loss area. Repeat for a total of five times, including the first application (1 ml). 5 times spray makes up 1 ml dose.



What precautions should be taken while applying TUGAIN MEN Solution?

- **TUGAIN MEN Solution** should be applied when the hair and scalp are thoroughly dry.
- Do not use a hairdryer to speed the drying of the topical solution because blowing air on the scalp may decrease the effectiveness of the drug.
- **TUGAIN MEN Solution** should be allowed to completely dry for 2 to 4 hours after applying it, including before going to bed.
- **TUGAIN MEN Solution** may stain clothing, hats or bed linen if the hair or scalp is not fully dry after using the medicine.
- **TUGAIN MEN Solution** should not be mixed with any hair oil nor should it be applied to other body parts. Hands should be thoroughly washed after application.

How long will you need to use TUGAIN MEN Solution?

Hereditary hair loss is a lifelong condition; hence, you will need to continuously use

TUGAIN MEN Solution to keep the hair regrowth. So, make it a part of your daily routine, just like brushing your teeth.

What happens if you completely stop using TUGAIN MEN Solution? Will you keep the regrown hair?

As previously MENTIONED, continuous use of **TUGAIN MEN solution** is needed to maintain hair regrowth. So, if you completely stop using **TUGAIN MEN Solution**, the normal hair loss process will start again. You will probably lose your regrown hair within 3 to 4 months.

What will happen if you forget to use TUGAIN MEN Solution and miss an application?

If you miss one or two applications of **TUGAIN MEN Solution**, just continue with the next application. Do not make up for missed applications by either increasing the dose of the next application or applying it more times than directed. But, do note — for definite and best results, applying **TUGAIN MEN Solution** every day needs to become a good habit just like brushing your teeth. So, try these tips:

- To help you stick to the twice-daily routine, try using **TUGAIN MEN Solution** at the same time every day. For example, in the morning, you could apply **TUGAIN MEN Solution** before putting on your shoes. At night, you could apply it before dinner.
- You can put up a reminder about using **TUGAIN MEN Solution** on the mirror that you look at most frequently, be it when combing your hair or dressing up.

Can TUGAIN MEN Solution be used more than two times a day? Will it work faster or better with more number of applications?

No. **TUGAIN MEN Solution** will not work faster or better if used more than two times a day. Rather, it may increase the chances of side effects.

Can TUGAIN MEN Solution be used in children or people over 65 years of age?

Not enough clinical evidence is available to support the use of minoxidil solution in children or people above 65 years of age. Hence, minoxidil solution should not be used in these patients.

What should you tell your doctor before using TUGAIN MEN Solution?

- Tell your doctor about medical problems you have now or had in the past. Inform your doctor if you have any heart problems. Patients should not use **TUGAIN MEN Solution** if they have a history of underlying coronary artery disease, cardiac dysrhythmias, congestive heart failure, or valvular heart disease. Patients with hypertension, including those under treatment with antihypertensive agents, should be monitored closely and their medication adjusted if necessary. **TUGAIN MEN Solution** should be used with caution in patients with any other cardiovascular disease present.
- In case you are on some medications, inform your doctor regarding the medicines you are taking with prescription and also without prescription.
- Some medicines may affect the way other medicines work.
- Your doctor will be able to guide you regarding which medications can be used with **TUGAIN MEN Solution**.
- You are a female patient of childbearing age/going to become pregnant.

What are the things to be considered while on TUGAIN MEN Solution therapy?

- Inform your doctor that you are on **TUGAIN MEN Solution** therapy before undergoing any laboratory tests, namely, blood or urine.
- Before taking any medicine, inform your doctor that you are using **TUGAIN MEN Solution**.
- If no improvement in hair growth is observed within 6 months of treatment, then consider talking to your doctor about stopping the treatment.
- Without consulting your doctor, do not change the dose or stop the treatment.
- **TUGAIN MEN Solution** is for external use only.
- **TUGAIN MEN Solution** is meant for application on the scalp area only.
- Do not exceed the total dose of 2 ml per day.
- It is not necessary to shampoo your hair before application of **TUGAIN MEN Solution**. However, if you have shampooed your hair, wait until your hair and scalp are dry. Also, after application, do not use a dryer as it may lower the efficacy of the drug. Let the medicine remain on your scalp for at least 4 hours after application; do not wash it off.
- Avoid contact with the eyes, ears, nose, mouth, and broken or irritated skin. If accidental contact occurs in such areas, wash the area with liberal amounts of water.

- Use along with other medications should be thoroughly discussed with your doctor.
- Do not use **TUGAIN MEN Solution** if you use other medicine on the scalp and/or your scalp is red, inflamed, infected, irritated, or painful.

Can TUGAIN MEN Solution be used when you are on other medications?

- People on medications for lowering blood pressure may experience a fall in blood pressure on standing. Such concerns/worries should be discussed with your doctor.
- Although it has not been clinically demonstrated, there exists the possibility of minoxidil potentiating orthostatic hypotension in patients concurrently taking guanethidine.

Are there any particular conditions under which you should stop using TUGAIN MEN Solution?

Stop use and consult your doctor in case of the following:

- Chest pain, rapid heartbeat, faintness or dizziness occurs.
- Sudden, unexplained weight gain occurs.
- Your hands or feet swell.
- Scalp irritation or redness occurs.
- Unwanted facial hair growth occurs. You do not see hair regrowth in 4 to 6 months.

What are the warnings and precautions to note when using TUGAIN MEN Solution?

- There is some absorption of minoxidil from the skin and potential exists for systemic effects such as tachycardia, angina, oedema or potentiation of the orthostatic hypotension produced by guanethidine.
- Patients should be observed periodically for any suggestions of the systemic effects of minoxidil.
- In the event of systemic side effects, discontinue administration of the drug. If necessary, fluid retention and oedema can be managed with diuretic treatment. Tachycardia and angina can be controlled by beta-adrenergic-blocking drugs or other sympathetic nervous system suppressants.
- Though not expected, finasteride, on percutaneous absorption, can suppress the serum DHT levels and may cause systemic side effects, that is, decreased libido, erectile dysfunction, ejaculation disorders, breast tenderness, or enlargement and testicular pain. Patients should be observed periodically for any suggestion of systemic effects.
- Especially, caution should be used in patients with liver function abnormalities as finasteride is metabolized extensively in the liver.
- Percutaneous absorption of finasteride may affect serum prostate-specific antigen (PSA) levels. These shall be taken into account for proper interpretation of serum PSA when evaluating MEN treated with **TUGAIN MEN Solution**.

What are the most common side effects?

TUGAIN MEN Solution, like all medicines, can have side effects but these don't necessarily affect everyone.

Tell your doctor, if you notice any of the following:

- Allergic-type reactions.
- Minor dermatologic reactions such as itching and irritation of the treated area of the scalp.
- Redness of the scalp where **TUGAIN MEN Solution** is being applied.
- Dry skin/scalp flaking.
- **TUGAIN MEN Solution** contains alcohol, which could cause burning or irritation in the eyes, mouth, nose and ears or sensitive skin areas.
- Sexual side effects such as impotence, decreased libido, ejaculation disorders, breast enlargement, or tenderness and skin rash.
- Excessive hair growth on other parts of the body
- Rapid heart rate.
- Swelling or puffiness of hands, face, ankles or stomach.
- Dizziness, lightheadedness or fainting.
- Problems with vision.
- Pain in the chest, arm or shoulder.
- Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipra.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.

What should be done if TUGAIN MEN Solution is accidentally swallowed?

If **TUGAIN MEN Solution** is accidentally swallowed, contact your doctor or nearest hospital immediately. The symptoms that you may experience are fast heart rate, low blood pressure (lightheadedness or fainting), and swelling or puffiness of the body.

Can TUGAIN MEN Solution produce unwanted hair growth?

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair, stop using **TUGAIN MEN Solution**. Over time, the unwanted hair, if caused by **TUGAIN MEN Solution**, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

1. Ensure that you apply **TUGAIN MEN Solution** only on the scalp area to be treated.
2. After applying **TUGAIN MEN Solution**, wash your hands well immediately.

When you apply **TUGAIN MEN Solution** at night, allow enough time for it to dry out before going to bed (usually 2 to 4 hours).

What is the most important information you should know about TUGAIN MEN Solution?

If you have heart disease, check with your doctor before using **TUGAIN MEN Solution**.

- Do not apply **TUGAIN MEN Solution** on any other part of the body.
- During application, take care that the solution does not come in contact with your eyes. In case of accidental contact, immediately wash your eyes with large amounts of cool tap water.

- It takes time to regrow hair. So, be patient because it will take twice-a-day usage for at least 4 to 6 months to show results.
- The amount of hair regrowth is different for each person.
- Some people have experienced changes in hair colour and/or texture.

In case of lack of time, can you apply TUGAIN MEN Solution and wash your hair an hour later?

No. For **TUGAIN MEN Solution** to work effectively, you should allow it to stay on the scalp for at least 4 hours before washing off.

What kind of shampoo should be used with TUGAIN MEN Solution?

If you wash your scalp before applying **TUGAIN MEN Solution**, use a mild shampoo.

Can you apply hair sprays, mousses, conditioners, gels, etc., while using TUGAIN MEN Solution?

Yes. You can use hair sprays or other styling aids on your hair while using **TUGAIN MEN Solution**. However, **TUGAIN MEN Solution** should be applied to the clean, dry scalp before other products are used.

Can you have your hair coloured or permed while using TUGAIN MEN Solution?

Yes. We have no evidence that these activities change the effect of **TUGAIN MEN Solution**. However, because hair colouring and perming can cause scalp irritation in certain people, we recomMEND the following precautions:

- To avoid possible scalp irritation, you should make sure that all of the **TUGAIN MEN Solution** has been washed off the hair and scalp before using colour or perm chemicals.
- For best results, on the day that you intend to colour, perm or use any other chemical treatMEnt on your hair, do not apply **TUGAIN MEN Solution** before or after such treatMEnt.
- Re-start your normal **TUGAIN MEN Solution** routine the next day. Do not use more **TUGAIN MEN Solution** to make up for the missed applications.

What should be done if the product appears yellow?

TUGAIN MEN Solution is clear and colourless; however, its colour may vary and, occasionally, it may have a yellow appearance. The colour of the solution does not affect its efficacy.

How should the TUGAIN MEN Solution be stored?

TUGAIN MEN Solution should be stored in a cool place away from light.

Where can further information on this product be obtained?

The information provided here is not the complete set of information. Please consult your doctor for further advice.

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