

**GROFULLY MENS EXTRA STRENGTH HAIR REGROWTH TREATMENT- minoxidil
5% solution
TTEM, Inc**

GROFULLY 5% Minoxidil Topical Solution

Minoxidil 5% w/v

Hair regrowth treatment for men

USE

to regrow hair on the top of the scalp (vertex only, see picture on side on carton)

For external use only.

Flammable: Keep away from fire or flame.

Do not use if

- Your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% topical solution is not intended for frontal baldness or receding hairline.
- You have no family history of hair loss
- Your hair loss is sudden and/or patchy
- You do not know the reason for your hair loss
- You are under 18 years of age. Do not use on babies or children.
- Your scalp is red, inflamed, infected, irritated, or painful
- You use other medicines on your scalp

Ask a doctor before use if you have heart disease

When using this product

- Do not apply on other parts of the body
- Avoid contact with eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- Some people have experienced change in hair color and/or texture.
- It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- The amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask doctor if

- 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 months

May be harmful if used when pregnant or breast-feeding.

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- Apply one mL with dropper 2 times a day directly onto the scalp in the hair loss area.
- Using more or more often will not improve results.
- Continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again.

Other Information

- See hair loss pictures on side of this carton
- Before use, read all information on carton and enclosed leaflet
- Keep the carton. It contains important information.
- Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- Store at controlled room temperature 68° to 77°F (20° to 25°C).

Alcohol, Propylene Glycol, Purified Water

Questions or comments

Call toll-free 1-800-559-7691

or visit grofully.com

PMS C

- Black
- 7466 C
- 3385 C
- 332 C



Drug Facts

Active Ingredient	Purpose
Minoxidil 5% w/v	Hair regrowth treatment for men

Use: To regrow hair on the scalp (vertex only, see picture on side on carton)

Warnings:
For external use only.
Flammable. Keep away from fire or flames.

Do not use if:
• Your amount of hair loss is different than that shown on the side of this carton or your hair has to be on the front of the scalp. • No known solution to not increase for normal (normal or normal) hair loss. • You have no family history of hair loss. • Your hair loss is sudden and/or patchy. • You do not have the reason for your hair loss. • You are under 18 years of age. • Do not use on any lesions and ulcers. • Your scalp is red, inflamed, itchy, burning, irritated, or painful. • You use other medicines on the scalp.

Ask a doctor before use if you have heart disease.

How to use:
• Do not apply to other parts of the body. • Avoid contact with the eyes. In case of accidental contact, flush eyes with large amounts of cool tap water. • Some people have experienced dizziness in their ears and/or water. • If hair loss is regrowing, it may occur in 2 months with further a day usage. For some men, you may need to use this product for at least 4 months before you see results. • The amount of hair regrowth is different for each person. This product will not work for all men.

Other uses and side effects:
• Chest pain, rapid heartbeat, dizziness, or dizziness occurs. • Sudden, unexplained weight gain occurs. • Your lips or feet swell. • Swell ankles or other parts of your body. • Unusual hair growth occurs. • You do not see hair regrowth in 4 months.

May be harmful if used while pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:
• Apply one mL, with dropper 2 times a day directly onto the scalp in the hair loss area.
• Using more or more often will not improve results.
• Continued use is necessary to increase and hold your hair regrowth, or hair loss will begin again.

Other Information:
• See hair loss picture on side of this carton. • Before use, read all information on carton and enclosed leaflet. • Keep this carton. It contains important information. • Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men. • In clinical studies of men with male pattern hair loss, men aged 18-40 years with moderate degrees of hair loss. • Minoxidil topical solution for men (previously marketed as Rogaine) has 5% minoxidil topical solution. • Store at controlled room temperature between 68° - 77° (20° - 25° C).

Inactive Ingredients: alcohol, polyethylene glycol, purified water

Questions or comments: Call toll-free 1-800-888-7981 or visit grofully.com

grofully.com
Hair at its fullest.

This Package Contains:

- One (1) 60 mL (2 FL. OZ.) One (1) 60 mL (2 FL. OZ.) bottle of 5% Minoxidil Topical Solution USP (one-month supply)
- One (1) 60 mL (2 FL. OZ.) bottle of 5% Minoxidil Topical Solution USP (one-month supply)

Information leaflet with complete directions on how to use and what to expect. (Read enclosed leaflet before use.)

GROFULLY™

5% Minoxidil Topical Solution, USP
Men's Extra Strength Hair Regrowth Treatment

Reactivates Hair Follicles To Stimulate Regrowth. Clinically Proven To Help Regrow Hair.

Unscented | Topical Solution
ONE MONTH SUPPLY
ONE 60mL (2 FL. OZ.) BOTTLE

For best results, apply directly to scalp. Use twice daily.

Grofully Extra Strength Hair Regrowth Treatment (5% Minoxidil Topical Solution USP) is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. 5% Minoxidil Topical Solution USP has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, 5% Minoxidil Topical Solution USP may not work.



Lot #
Exp

Rev 16/21

Manufactured for:
TDM, LLC
1490 West Palmetto Park Road,
Suite 111
Boca Raton, FL 33486

GROFULLY MENS EXTRA STRENGTH HAIR REGROWTH TREATMENT

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70150-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70150-007-01	1 in 1 BOX	01/24/2022	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	01/24/2022	

Labeler - TTEM, Inc (079997910)

Revised: 1/2022

TTEM, Inc