

**GROFULLY WOMENS HAIR REGROWTH TREATMENT- minoxidil 2% solution
TTEM, Inc**

GROFULLY - 2% Minoxidil Topical Solution

Minoxidil 2% w/v

Hair regrowth treatment

USE

to regrow hair on scalp

For external use only

Flammable: Keep away from fire or flame

Do not use if

- Your degree of hair loss is different than that shown on this carton, because this product may not work for you
- You have no family history of hair loss
- Your hair loss is sudden and/or patchy
- Your hair loss is associated with childbirth
- 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. You may need to use this product 2 times a day for at least 4 months before you see results.
- The amount of hair regrow is different for each person. This product will not work for all women..

Stop use and ask a doctor if

- Chest pain, rapid heartbeat, faintness, or dizziness occurs
- Sudden, unexplained weight gain occurs
- Your hand 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 1 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.
- In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solutions was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth: 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth: 33% had minimal regrowth).
- Store at controlled room temperature 68 ° - 77 °F (20 ° - 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: Minoxidil 2% USP. **Purpose:** Hair regrowth treatment.

Use to regrow hair on the scalp.

Warnings

- For external use only.
- Flammable. Keep away from fire or flame.
- Do not use if:
 - You have a degree of hair loss different from that shown on the side of this carton, because this product may not work for you.
 - 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.
 - Your hair loss is associated with childhood.
 - You are under 18 years of age.
 - Do not use on balding and children.
 - Your scalp is red, inflamed, infected, irritated, or painful.
 - You use other medications on the 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 the eyes. In case of accidental contact, close eyes with large amounts of cool tap water.
- Some people have experienced changes in hair color and/or texture.
- It takes time to regrow hair. You may need to use this product 2 times a day 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 women.
- Stop use and ask a doctor if:
 - Chest pain, rapid heartbeat, faintness, or dizziness occurs.
 - Sudden, unexplained weight gain occurs.
 - Four hands or feet swell.
 - Scalp irritation or redness occurs.
 - Unexplained facial hair growth occurs.
 - You do not see hair regrowth in 4 months.

May be harmful if used when 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 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 this carton. It contains important information. In clinical studies of healthy white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (18% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil, for 8 months. The hair that regrows naturally, the liquid without minoxidil, is lost for 6 months. The hair that regrows naturally, 23% had minimal regrowth. Sites of controlled room temperature between 60° - 77°F (15° - 25° C).

Inactive ingredients: alcohol, polyethylene glycol, purified water.

Questions or comments: call toll-free 1-800-558-7661 or visit grofully.com



Lot #
Exp

grofully.com
Hair at its fullest.



GROFULLY™
2% Minoxidil Topical Solution, USP
Women's 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 Hair Regrowth Treatment (2% Minoxidil Topical Solution USP) is for women who have a general thinning of hair on the top of the scalp. Not intended for frontal baldness or a receding hairline. 2% Minoxidil Topical Solution USP has been shown to regrow hair in women with the following degrees of thinning hair or hair loss.



If women have more hair loss or hair loss in a place different than shown above, 2% Minoxidil Topical Solution USP may not work.

Manufactured for:
TMM, LLC
1493 West Palmetto Park Road,
Suite 111
Boca Raton, FL 33486

GROFULLY WOMENS HAIR REGROWTH TREATMENT

minoxidil 2% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70150-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 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:70150-006-01	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	ANDA078176	01/24/2022	

Labeler - TTEM, Inc (079997910)

Revised: 1/2022

TTEM, Inc