

# **ROOTLY HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% solution TTEM, LLC**

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**Rootly Hair Regrowth Treatment 2% Minoxidil**

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 everyone.

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

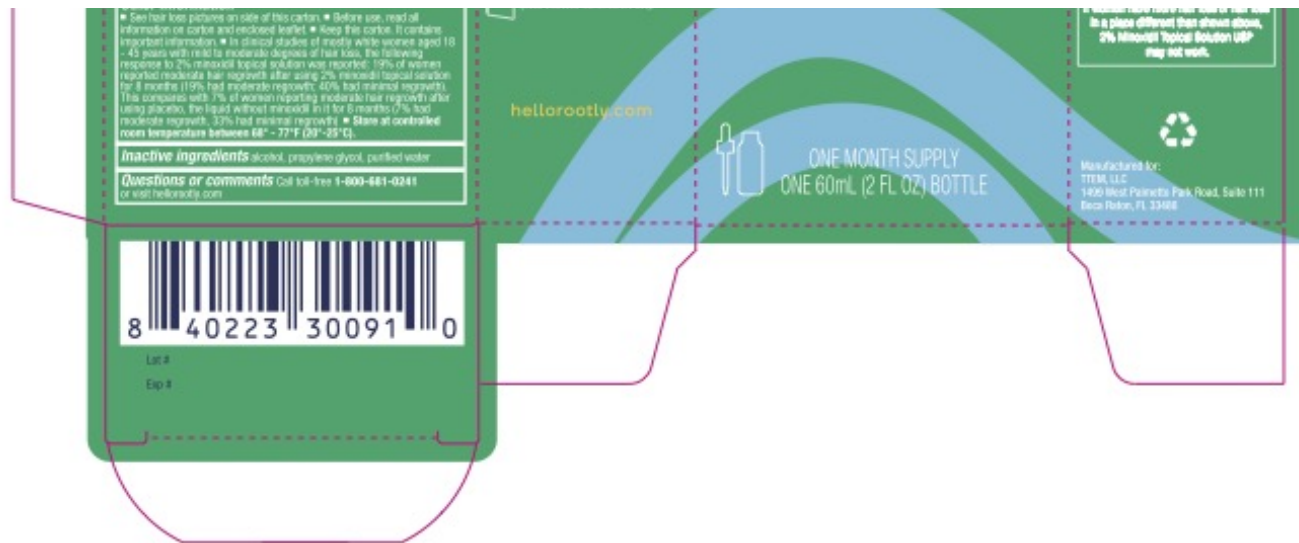
- See hair loss pictures on side of this carton
- Before use, read all information on carton and enclosed leaflet
- Keep the carton. It contains important information.
- In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% 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).


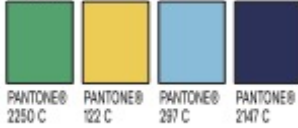



Alcohol, Propylene Glycol, Purified Water

Questions or comments

Call toll-free 1-800-681-0241 or visit [hellorootly.com](http://hellorootly.com)





 <p><b>Sterling</b> p -1 515 421-2210 sterlingbrands.com 700 W Pete Rose Way Suite 460 Cincinnati, OH 45205</p> <p>INTERNAL PROJECT #: 16181874 LOG #: 87401</p>	CLIENT / BRAND / SKU DESCRIPTION / SKU NUMBER Rootly / Minoxidil / Womens 2% Carton /840223300910		REVISION NO: 4 RELEASE DATE: 6/29	MECHANICAL
	PRINTER Not Supplied	PRINT METHOD <input type="checkbox"/> FLEXO <input checked="" type="checkbox"/> LITHO <input type="checkbox"/> ROTO <input type="checkbox"/> DIGITAL <input type="checkbox"/> DRY OFFSET <input type="checkbox"/> OTHER <input type="checkbox"/> NOT SPECIFIED		05.05.2021 DESIGNER: bh/jc
	PROCESS COLORS	LINE COLORS 	SUBSTRATE 	<b>FONTS - See Release Document for fonts list.</b> In the event of any modifications or revisions to this artwork or use of these fonts for other purposes, the client, production house, separator/repco agency, pre-press service bureau and/or printer must purchase appropriate Font Software licenses covering all users.  <b>LIABILITY</b> Client assumes all responsibility for proofreading, reviewing and correcting final artwork before release and for submission to state and regulatory agencies and print vendors.
	PROCESS MATCH COLORS 	FINISHES 		

## ROOTLY HAIR REGROWTH TREATMENT FOR WOMEN

minoxidil 2% solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70150-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL

### Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70150-004-01	1 in 1 BOX	08/22/2021	
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	08/22/2021	

**Labeler** - TTEM, LLC (079997910)

Revised: 1/2023

TTEM, LLC