

**ROOTLY EXTRA STRENGTH HAIR REGROWTH TREATMENT FOR MEN- minoxidil
5% solution
TTEM, LLC**

Rootly Extra Strength Hair Regrowth Treatment for Men

Minoxidil 5% w/v

Hair regrowth treatment for men

USE

to regrow hair on the top of the scalp

For external use only.

Flammable: Keep away from fire or flame.

Do not use if

- You are a woman
- 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. For some men, 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 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).


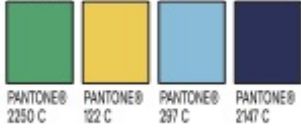


Alcohol, Propylene Glycol, Purified Water

Questions or comments

Call toll-free 1-800-681-0241 or visit hellorootly.com





 Sterling p -1 513 421-2210 sterlingbrands.com 700 W Pete Rose Way Suite 460 Cincinnati, OH 45205 INTERNAL PROJECT #: 16181874 LOG #: 87403	CLIENT / BRAND / SKU DESCRIPTION / SKU NUMBER Rootly / Minoxidil / Mens 5% Carton /840223300828		REVISION NO: 3 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
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ROOTLY EXTRA STRENGTH HAIR REGROWTH TREATMENT FOR MEN

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70150-005
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)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70150-005-01	1 in 1 BOX	08/24/2021	
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	ANDA076239	08/24/2021	

Labeler - TTEM, LLC (079997910)

Revised: 1/2023

TTEM, LLC