

**ROOTS PROFESSIONAL - TOPICAL SOLUTION HAIR REGROWTH TREATMENT-  
minoxidil 5% solution  
Roots Hair Club, LLC**

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**Roots Professional - 5% Minoxidil Topical Solution Hair Regrowth Treatment**

Minoxidil 5% w/v

Hair regrowth treatment for men

**USE**

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

For external use only. For use by men only.

Flammable: Keep away from fire or flame

Do not use if:

- You are a woman
- Your amount of hair loss is different than shown on the side of this carton or hair loss is on the front of the scalp, 5% minoxidil 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 the scalp

Ask your 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, rinse 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. 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 a doctor if

- Chest pain, rapid heart beat, faintness, or dizziness occurs
- Sudden, unexplained weight gain occurs
- Your hands or feet swell
- Scalp irritation or redness occurs
- You get unwanted facial hair growth
- You do not see hair regrowth in 4 months

## DIRECTIONS

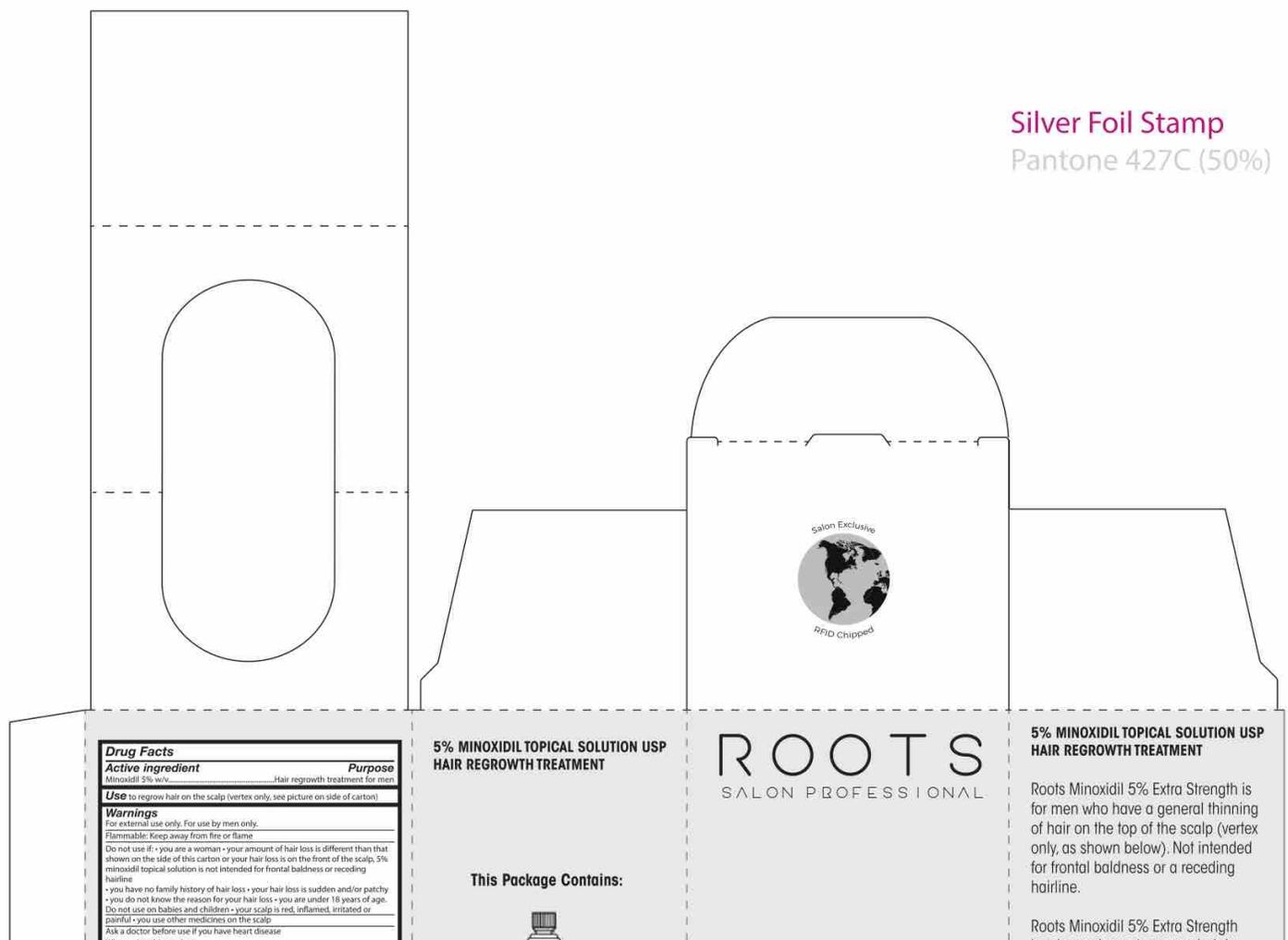
- apply 1mL with sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again
- See hair loss pictures on the side of this carton
- 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 provide more hair regrowth than 2% minoxidil topical solution
- Store at controlled room temperature 20 ° to 25 ° C (68 ° to 77 ° F)

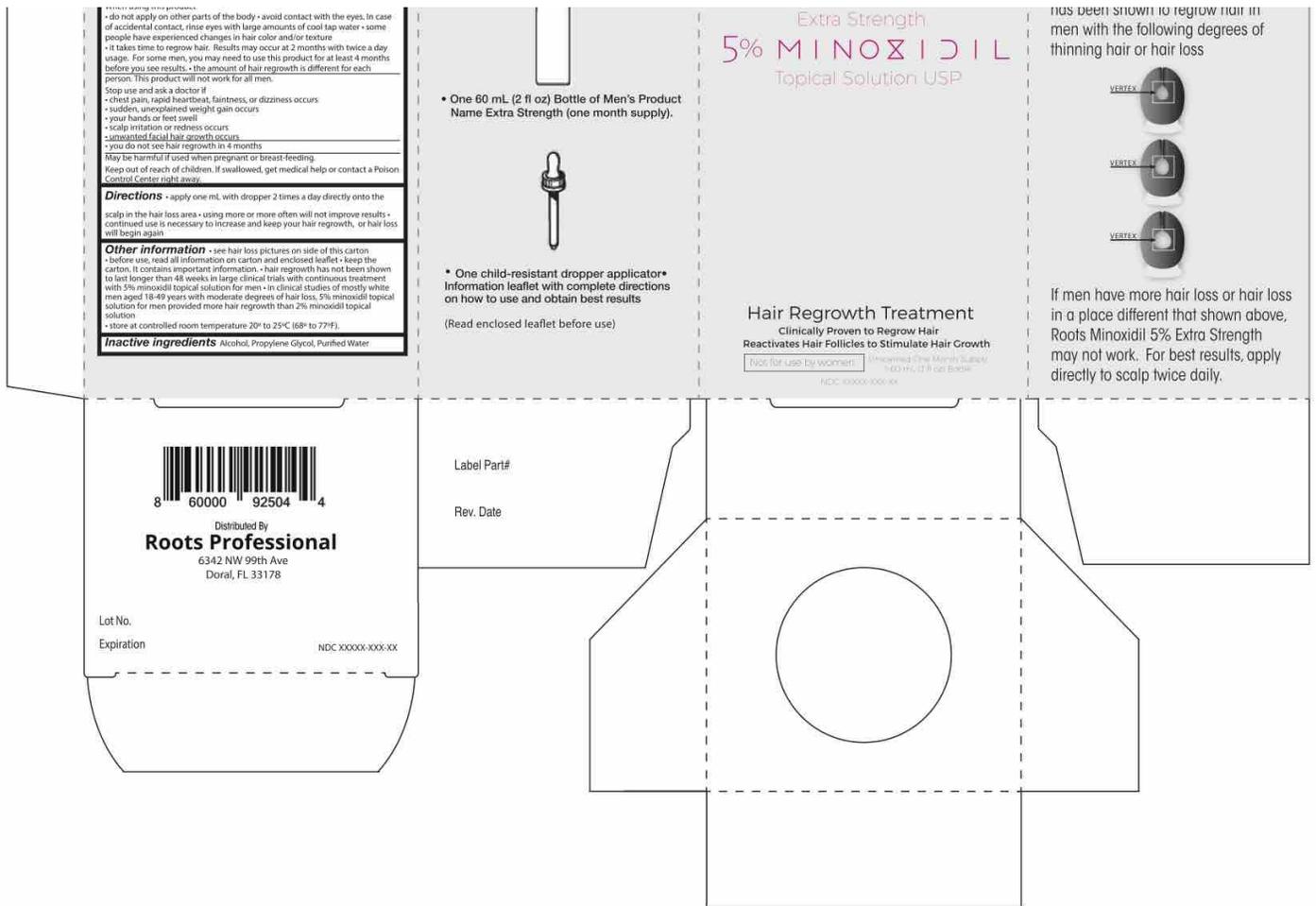
Alcohol, Propylene Glycol, Purified Water

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

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

Silver Foil Stamp  
Pantone 427C (50%)





# ROOTS PROFESSIONAL - TOPICAL SOLUTION HAIR REGROWTH TREATMENT

minoxidil 5% solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73359-002
<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	5 g in 100 mL

## Inactive Ingredients

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73359-002-01	1 in 1 BOX	09/11/2019	
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	09/11/2019	

**Labeler** - Roots Hair Club, LLC (117159782)

Revised: 1/2023

Roots Hair Club, LLC