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

Club Roots - 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 expereinced 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 dissiness occurs
- Sudden, unexplained weight gain occurs
- Your hands of feet swell
- Scalp irritation or redness occurs
- You get unwanted facial hair growth
- You do not see hair regrowth in 4 months

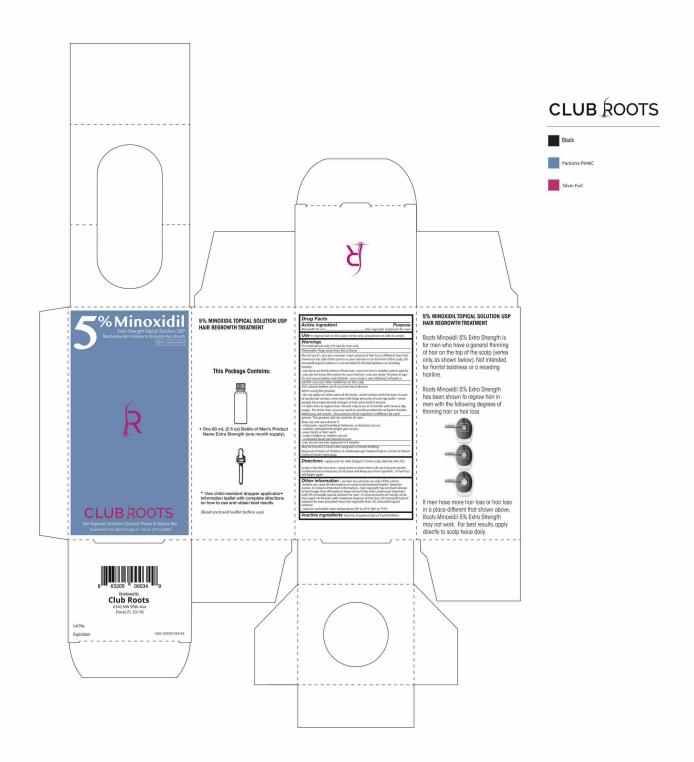
DIRECTIONS

- 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 trialse with continuous treatment with 5% minoxidil topical solution for men
- In clincial 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.



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minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73359-001
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	
WATER (UNII: 059QF0KO0R)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:73359-00	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