

**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 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.

CLUB ROOTS

- Black
- Pantone P6-66C
- Silver Foil



**5% MINOXIDIL TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT**

Roots Minoxidil 5% Extra Strength is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline.

Roots Minoxidil 5% Extra Strength has been shown to regrow hair in men with the following degrees of thinning hair or hair loss



If men have more hair loss or hair loss in a place different that shown above, Roots Minoxidil 5% Extra Strength may not work. For best results, apply directly to scalp twice daily.

5% Minoxidil
Extra Strength Topical Solution, USP
Reactivates Hair Follicles to Stimulate Hair Growth

**5% MINOXIDIL TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT**

This Package Contains:



• One 60 mL (2 fl oz) Bottle of Men's Product Name Extra Strength (one month supply).



• One child-resistant dropper applicator*
Information leaflet with complete directions on how to use and obtain best results
(Read enclosed leaflet before use)

Drug Facts	Purpose
Active ingredient Minoxidil 5% (w/v)	Hair regrowth treatment for men
Use Apply to clean, dry scalp twice daily. See picture on side of carton.	
Warnings For external use only. For use by men only. Discontinue use once hair begins to fall out. Do not use if - you are a woman - your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. This 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 and children - your scalp is red, inflamed, itchy or - if bald - you use other medicines 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, rinse eyes with large amounts of cool tap water - women: people have experienced changes in hair color and/or texture - it takes time to regrow hair. Results may occur in 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: - head, face, rapid heartbeat, dizziness, or dizziness occurs - sudden, unexplained weight gain occurs - scalp irritation or redness occurs - prolonged hair regrowth occurs - you do not see hair regrowth in 4 months. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center near you.	
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 that loss will begin again.	
Other information - see hair loss picture on side of this carton. Caution: Read all information on carton and enclosed leaflet - keep the bottle upright in original container. Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with the minoxidil topical solution for men. In clinical studies of steady-state 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 20° to 25°C (68° to 77°F).	
Inactive ingredients Alcohol, Fragrance, Glycerin, Purified Water	

CLUB ROOTS
Hair Regrowth Treatment Clinically Proven to Regrow Hair
Unadorned 1.1 One Month Supply / 1.60 mL (2 fl oz) Bottle



Distributed by
Club Roots
6342 NW 99th Ave
Doral, FL 33178

Lot No.
Expiration NDC: 73359-001

CLUB ROOTS - TOPICAL SOLUTION HAIR REGROWTH TREATMENT

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73359-001
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Route of Administration	TOPICAL
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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:73359-001-01	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)