GROWELL MENS HAIR REGROWTH TREATMENT 5 MINOXIDIL- minoxidil liquid APIRA SCIENCE, INC.

GROWELL Men's Hair Regrowth Treatment 5% Minoxidil

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment for men

Use

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

Warnings

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 that shown on the side of this carton or your 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 and children
- your scalp is red, inflamed, infected, irritated or painful
- 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 the other parts of the body
- avoid contact with the eyes. In caes 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 heartbeat, faintness, or dizziness occurs
- scalp irritation or redness occurs
- sudden, unexplained weight gain occurs
- unwanted facial hair growth occurs
- your hands or feet swell
- you do not see hair regrowth in 4 months

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

Keep out of reach of children.

If swallowed, get medical help, or contact a Poison Contrl Center right away.

Directions

- apply one mL with dropper 2 times a daydirectly on to 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, reatd 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 more hair regrowth than 2% minoxidiltopical solution
- store at controlled room temperature 20° to 25°C (68° to 77°F).

Inactive ingredients

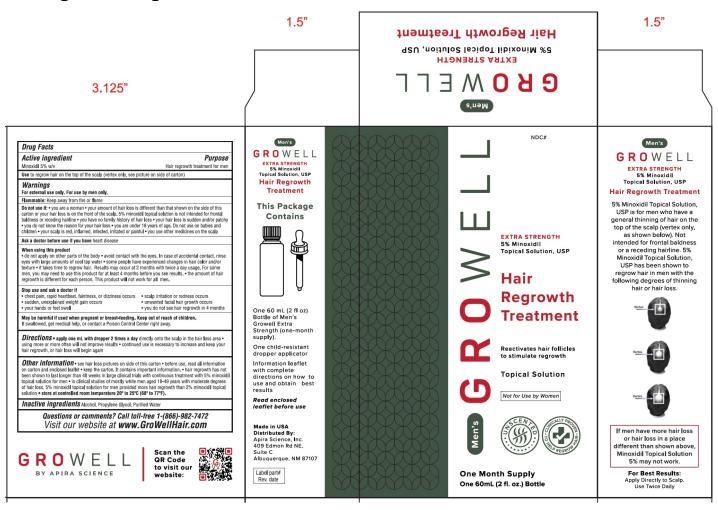
Alcohol, Propylene Glycol, Purified Water

Questions or comments?

Call toll-free 1-(866)-982-7472

Visit our website at www.GroWellHair.com

Package Labeling:



GROWELL MENS HAIR REGROWTH TREATMENT 5 MINOXIDIL

minoxidil liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84329-465	
Route of Administration	TOPICAL			

Active Ingredient/Active Molety				
Ingredient Name	Basis of Strength	Strength		
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 mL		

Inactive Ingredients			
Strength			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:84329- 465-00	1 in 1 BOX	03/04/2024			
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA076239	03/04/2024			

Labeler - APIRA SCIENCE, INC. (010514721)

Revised: 5/2024 APIRA SCIENCE, INC.