

**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 cases 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 Control Center right away.

Directions

- **apply one mL with dropper 2 times a day** directly 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, 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 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:

3.125"

Drug Facts	
Active ingredient	Purpose
Minoxidil 5% w/v	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 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.	
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• 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 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 20° to 25°C (68° to 77°F).	
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Questions or comments? Call toll-free 1-(866)-982-7472 Visit our website at www.GroWellHair.com	

Scan the QR Code to visit our website:

1.5"

Men's

GROWELL

EXTRA STRENGTH
5% Minoxidil
Topical Solution, USP

Hair Regrowth Treatment

This Package Contains

One 60 mL (2 fl oz) Bottle of Men's GroWell 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

Made in USA
Distributed By:
Apira Science, Inc.
409 Edmon Rd NE,
Suite C
Albuquerque, NM 87107

Label part#
Rev. date

1.5"

GROWELL

Men's

GROWELL

EXTRA STRENGTH
5% Minoxidil
Topical Solution, USP

Hair Regrowth Treatment

Reactivates hair follicles to stimulate regrowth

Topical Solution

Not for Use by Women

One Month Supply
One 60mL (2 fl. oz.) Bottle

Men's

GROWELL

EXTRA STRENGTH
5% Minoxidil
Topical Solution, USP

Hair Regrowth Treatment

5% Minoxidil Topical Solution, USP 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. 5% Minoxidil Topical Solution, USP 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 than shown above, Minoxidil Topical Solution 5% may not work.

For Best Results:
Apply Directly to Scalp.
Use Twice Daily

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 Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

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.