

**GROWELL WOMENS HAIR REGROWTH TREATMENT 2 MINOXIDIL-
minoxidil liquid
APIRA SCIENCE, INC.**

GROWELL Women's Hair Regrowth Treatment 2% Minoxidil

Drug Facts

Active ingredient

Minoxidil 2% w/v

Purpose

Hair regrowth treatment

Use

to regrow hair on the top of the scalp

Warnings:

For external use only.

Flammable:Keep away from fire or flame

Do not use if:

- your degree of hair loss is different than shown on the side of this carton because this product may not work on you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- 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 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. 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 everyone.

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 women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: (19% of women reporting moderate hair regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- **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

Package Labeling:

3.125"
1.5"
1.5"

Drug Facts

Active ingredient Minoxidil 2% w/v	Purpose Hair regrowth treatment
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Warnings: For external use only.
Flammable: Keep away from fire or flame.

Do not use it:
• your degree of hair loss is different than that shown on the side of this carton, because this product may not work for you • you have no family history of hair loss • your hair loss is sudden and/or patchy • your hair loss is associated with childhood • 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. You may need to use this product 2 times a day 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 everyone.

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.
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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

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Visit our website at www.GroWellHair.com

Scan the QR Code to visit our website:

Women's
GROWELL
2% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

This Package Contains:

One 60 mL (2 fl oz) Bottle of women'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:
Apra Science, Inc.
409 Edmon Rd NE,
Suite C
Albuquerque, NM 87107

Label part#
Rev. date

Women's
GROWELL
2% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

2% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

2% Minoxidil Topical Solution, USP is for women 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 women have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Solution 5% may not work.

Do not use if you have patchy hair loss as shown above.

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

GROWELL WOMENS HAIR REGROWTH TREATMENT 2 MINOXIDIL			
minoxidil liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84329-466
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 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:84329-466-00	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	ANDA078176	03/04/2024	

Labeler - APIRA SCIENCE, INC. (010514721)

Revised: 5/2024

APIRA SCIENCE, INC.