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

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### 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 that 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 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 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).

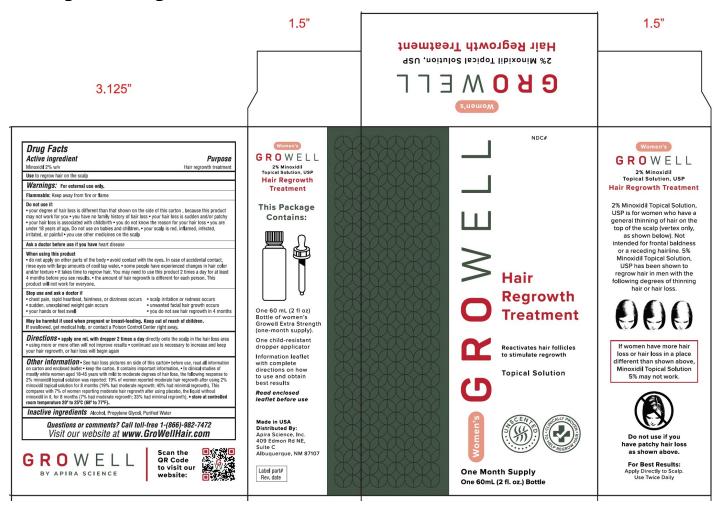
# Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

**Questions or comments?** 

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

#### **Package Labeling:**



# **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	<b>Basis of Strength</b>	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)		

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l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> 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.