

MINOXIDIL- minoxidil solution
H2-Pharma, LLC

Minoxidil Topical Solution

Drug Facts

Active ingredient

Minoxidil, USP 2% w/v

Purpose

Hair regrowth treatment

Use

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

Warnings

For external use only

Flammable: Keep away from fire or flame

Do not use if

- 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
- 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
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- 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 (1-800-222-1222) 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.
- in clinical studies of mostly white men aged 18 to 49 years with moderate degrees of hair loss, the following response to minoxidil topical solution 2% for men was reported: 26% of men reported moderate to dense hair regrowth after using minoxidil topical solution 2% for men for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).
- store at controlled room temperature 20° to 25°C (68° to 77°F)

Inactive ingredients

alcohol (60% v/v), propylene glycol, purified water

Questions?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

NDC 61269-066-75

*Compare to the active ingredient in

Men's Rogaine®

FOR MEN

Minoxidil

Topical Solution,

USP 2%

Hair regrowth treatment

Reactivates hair follicles to stimulate regrowth

Clinically proven to help regrow hair

Unscented

FOR BEST RESULTS

Apply directly to scalp twice daily

TWO MONTH SUPPLY

Two 60 mL (2 fl oz) bottles

H² pharma

FOR MEN

Minoxidil Topical Solution, USP 2%

Hair regrowth treatment

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Minoxidil Topical Solution, USP 2%

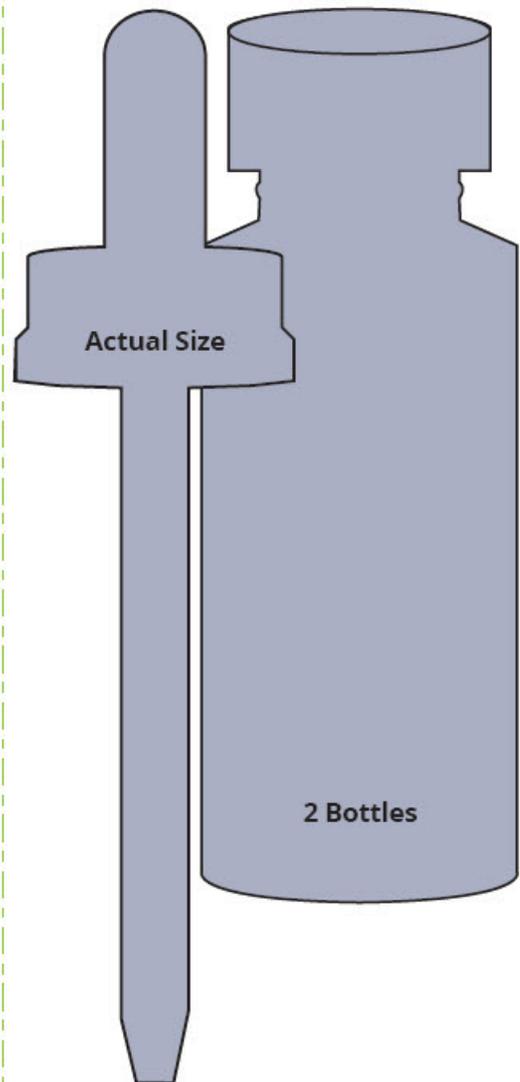
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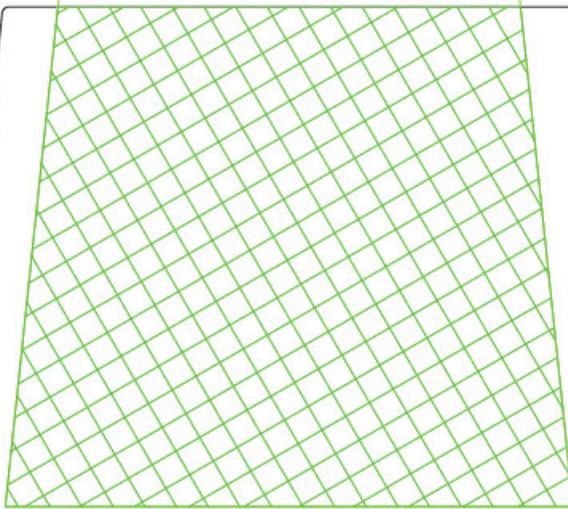
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TWO MONTH SUPPLY
Two 60 mL (2 fl oz) bottles





Lot:
Exp:



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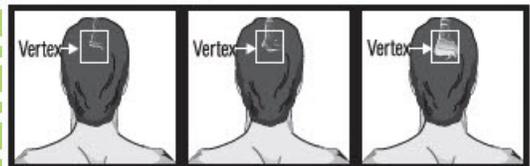
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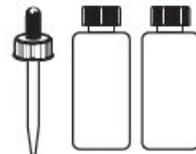
Minoxidil Topical Solution is for men who have a general thinning of hair on the top of the scalp (vertex) as shown. Minoxidil Topical Solution has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss than shown above, Minoxidil Topical Solution may not work.

This Package Contains:

- Two 60 mL (2 fl oz) bottles of Minoxidil Topical Solution (two month supply).
- One child-resistant dropper applicator.
- Information leaflet with complete directions on how to use and obtain best results.



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Inactive Ingredients alcohol (60% v/v), propylene glycol, purified water

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*This product is not affiliated with, manufactured by, or produced by the makers or owners of Rogaine®.

Distributed by: **H2-Pharma, LLC**
 Montgomery, AL 36117
 www.h2-pharma.com

MINOXIDIL

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61269-066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 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:61269-066-73	1 in 1 CARTON	12/06/2023	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:61269-066-75	2 in 1 CARTON	12/06/2023	
2		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	ANDA074588	12/06/2023	

Labeler - H2-Pharma, LLC (028473634)

Revised: 12/2023

H2-Pharma, LLC