

**MINOXIDIL- minoxidil solution**  
**H2-Pharma, LLC**

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**Minoxidil Topical Solution**

***Drug Facts***

**Active ingredient**

Minoxidil, USP 5% w/v

**Purpose**

Hair regrowth treatment for men

**Use**

to regrow hair on the top of the scalp (vertex only, see pictures 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. Minoxidil topical solution 5% 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.

### **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.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with minoxidil topical solution 5% for men
- in clinical studies with mostly white men aged 18 to 49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%
- store at controlled room temperature 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

alcohol (30% v/v), propylene glycol (50% v/v), 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 61269-094-75

\*Compare to the active ingredient in  
Men's Rogaine®

FOR MEN  
EXTRA STRENGTH

Minoxidil  
Topical Solution,  
USP 5%  
Hair regrowth treatment

Reactivates hair follicles to stimulate regrowth  
Clinically proven to help regrow hair  
Unscented

NOT FOR USE BY WOMEN

FOR BEST RESULTS  
Apply directly to scalp twice daily

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

H<sup>2</sup> pharma

FOR MEN  
EXTRA STRENGTH

# Minoxidil Topical Solution, USP 5% Hair regrowth treatment

NDC 61269-094-75

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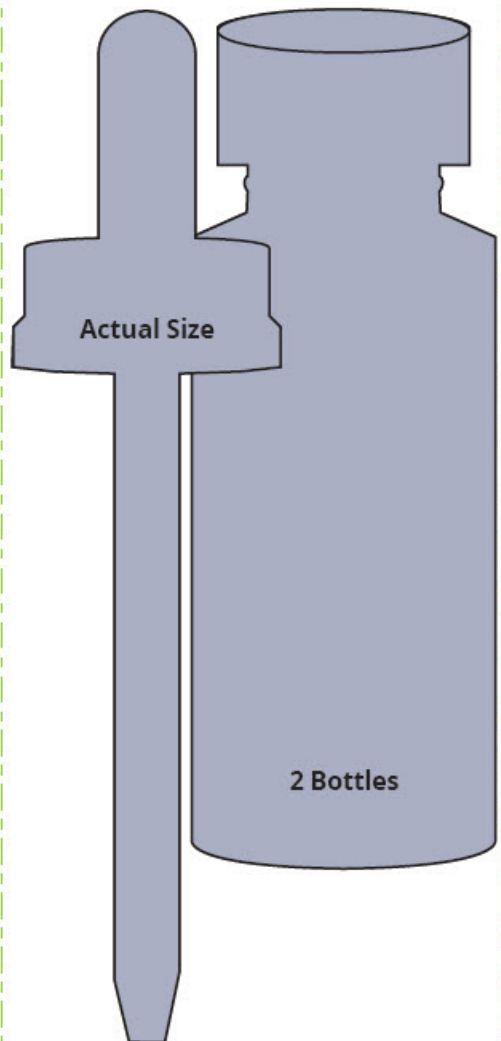
**NOT FOR USE BY WOMEN**

**FOR BEST RESULTS**  
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**TWO MONTH SUPPLY**  
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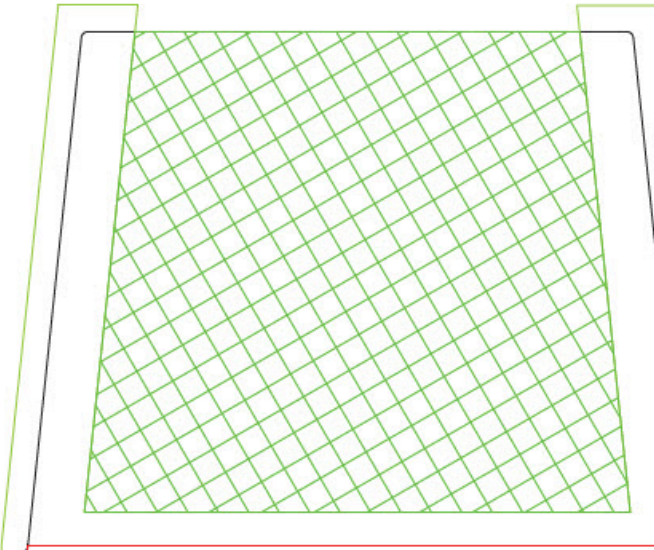
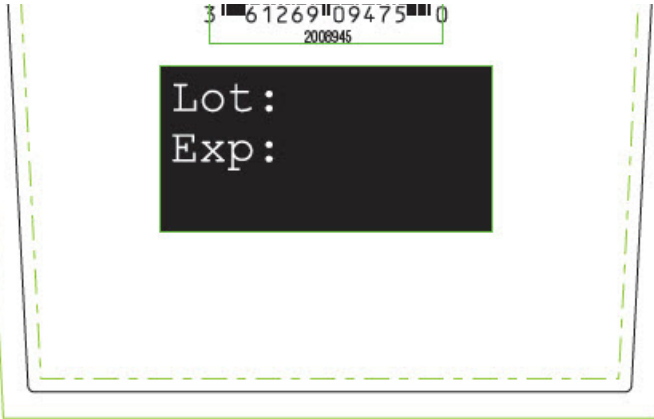


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**Drug Facts**

**Active ingredient** **Purpose**  
Minoxidil, USP 5% w/v.....Hair regrowth treatment for men

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

**Warnings**

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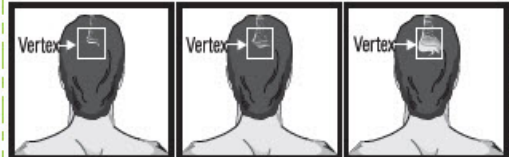
**Other information**

- see hair loss pictures on side of this carton
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- keep the carton. It contains important information.

**Not For Use By Women:**

May grow facial hair. May be harmful if used during pregnancy or breast-feeding.

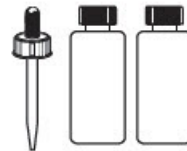
Minoxidil Topical Solution 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil Topical Solution 5% for men has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Solution 5% for men may not work.

**This Package Contains:**

- Two 60 mL (2 fl oz) bottles of Minoxidil Topical Solution 5% (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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**Questions?** Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

\*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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61269-094
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 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
	NDC 61269			

1	NDC:61269-094-73	1 in 1 CARTON	04/25/2022	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:61269-094-75	2 in 1 CARTON	04/25/2022	
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	ANDA075518	04/25/2022	

**Labeler** - H2-Pharma, LLC (028473634)

Revised: 4/2022

H2-Pharma, LLC