

**HAIR REGROWTH TREATMENT EXTRA STRENGTH FOR MEN- minoxidil solution**  
**Seiseidou America, Inc.**

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**Minoxidil Topical Solution for Men**

***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

**Principal display panel**

FOR MEN

EXTRA STRENGTH

NOT FOR USE BY WOMEN

# MINOXIDIL TOPICAL SOLUTION, USP 5%

## Hair Regrowth Treatment

FOR BEST RESULTS APPLY DIRECTLY TO SCALP TWICE DAILY

FOR EXTERNAL USE ONLY

ONE MONTH SUPPLY - ONE 60 mL (2fl oz) BOTTLE

Distributed by Seiseidou America

10880 Wilshire Blvd., Suite 1101

Los Angeles, CA 90024

### Package label

**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, dizziness, or dizziness occurs  
• rash, 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 (50% v/v), propylene glycol (50% v/v), purified water

**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.

Vertex Vertex Vertex

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:**  
• ONE 60 mL (2 fl oz) BOTTLE OF MINOXIDIL TOPICAL SOLUTION 5% (ONE MONTH SUPPLY).  
• ONE CHILD-RESISTANT DROPPER APPLICATOR.  
• INFORMATION LEAFLET WITH COMPLETE DIRECTIONS ON HOW TO USE AND OBTAIN BEST RESULTS.

Distributed by Seiseidou America  
10880 Wilshire Blvd., Suite 1101  
Los Angeles, CA 90024

Questions or comments?  
Visit our website at [fortero.com](http://fortero.com)  
or email [support@fortero.com](mailto:support@fortero.com)

**Fortero**

NDC 82269-607-02  
FOR MEN  
EXTRA STRENGTH  
NOT FOR USE BY WOMEN

ACTUAL SIZE

1 BOTTLE

**MINOXIDIL TOPICAL SOLUTION, USP 5%**  
Hair Regrowth Treatment

FOR BEST RESULTS APPLY DIRECTLY TO SCALP TWICE DAILY  
FOR EXTERNAL USE ONLY  
ONE MONTH SUPPLY - ONE 60 mL (2 fl oz) BOTTLE

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**Lot:**  
**Exp:**

### FORTERO Hair Regrowth Treatment

## HAIR REGROWTH TREATMENT EXTRA STRENGTH FOR MEN

minoxidil solution

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:82269-607

**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:82269-607-02	1 in 1 CARTON	10/15/2021	
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	ANDA075518	10/15/2021	

**Labeler** - Seiseidou America, Inc. (112929084)

Revised: 11/2022

Seiseidou America, Inc.