

**BOURN HAIR REGROWTH TREATMENT FOR MEN- minoxidil 5% solution
Octri, Inc.**

ourn Minoxidil Topical Solution, USP 5% - Hair Regrowth Treatment for Men

Minoxidil 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)

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 right away. (1-800-222-1222)

DIRECTIONS

- apply 1 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 5% minoxidil topical solution for men

- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5%

for men provided more hair regrowth than minoxidil topical solution 2%

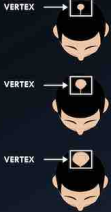
- store at controlled room temperature 20° to 25°C (68° to 77°F)

alcohol, propylene glycol, purified water

Questions or comments? (909) 517-1177

MINOXIDIL TOPICAL SOLUTION USP, 5%

Minoxidil topical solution USP 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shadow below). Not intended for frontal baldness or receding hairline. Minoxidil topical solution USP 5% 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 USP 5% may not work.

**FOR BEST RESULTS
USE TWICE DAILY**
APPLY DIRECTLY TO SCALP

BOURN™

EXTRA STRENGTH FOR MEN

MINOXIDIL

TOPICAL SOLUTION USP, 5%
HAIR REGROWTH TREATMENT

UNSCENTED
- Clinically Proven to Help Regrow Hair
- Reactivates Hair Follicles to Stimulate Regrowth
- Topical Solution



6 x 60 mL (2 FL OZ) SEALED BOTTLES
TOTAL 360 mL (12 FL OZ)
Not For Use By Women

6 Month Supply



Individually Sealed Bottles

THIS PACKAGE CONTAINS:
- Six 60 mL (2 fl oz) Individually Sealed Bottles of Extra Strength 5% Minoxidil Topical Solution.
- One child-resistant dropper applicator.
- Information leaflet with complete directions on how to use and obtain best results.
Read enclosed leaflet before use.

Drug Facts

Active Ingredient
Minoxidil 5%, w/v Hair regrowth treatment for men.

Purpose
Use to regrow hair on 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, irritated, infected, itchy, or painful.
• You use other medicines on the scalp.

Ask doctor before use if you have heart disease.

When using this product
• Do not apply to 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.

• If 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 doctor if
• Chest pain, rapid heartbeat, lightheadedness, or dizziness occurs.
• Swollen, 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.

Drug Facts (continued)

May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. (1-800-232-1233)

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 the "see 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 of mostly white men aged 18-40 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%.

Inactive ingredients

Alcohol, polyethylene glycol, purified water.

Questions or comments? (800) 517-1177

Made in USA
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www.bournhairregrowth.com



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BOURN HAIR REGROWTH TREATMENT FOR MEN

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81553-001
Route of Administration	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
ISOPROPYL ALCOHOL (UNII: ND2M41630Z)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81553-001-01	6 in 1 BOX	02/04/2021	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076239	02/04/2021		

Labeler - Octri, Inc. (070111400)

Revised: 1/2023

Octri, Inc.