BOSLEY MD EXTRA STRENGTH FOR MEN- minoxidil 5% solution Scientific Hair Research, LLC

Bosley MD Extra Strength for Men Minoxidil Topical Solution 5%

Minoxidil 5% w/v

Hair regrowth treatment for men

USE

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 dierent than that shown on the side of this carton, or your hair loss is on the front of the scalp. 5% Minoxidil Topical Solution 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

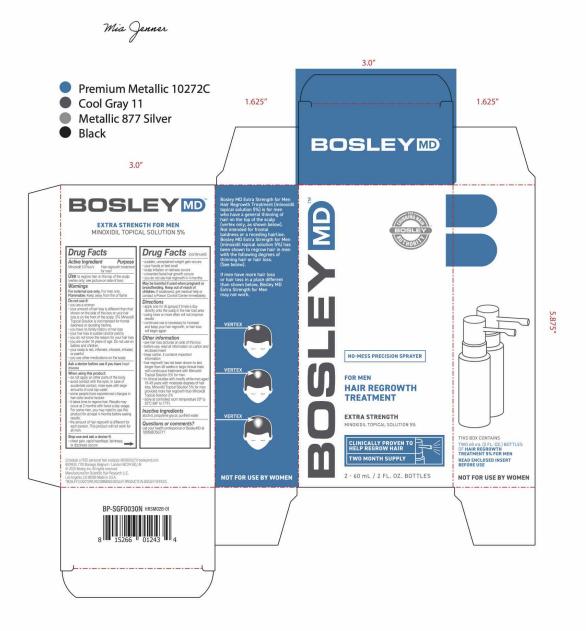
- Apply one mL (6 sprays) 2 times a day directly onto the scalp in the area of hair loss
- Using more or more often will not improve results
- Continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again.
- See hair loss pictures on side of this carton
- Before use, read all information on carton and enclosed leaflet
- Keep this 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 18-19 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- Store at controlled room temperature between 68° 77°F (20°-25°C).

Alcohol, Propylene Glycol, Purified Water

Questions or comments? Call your helath professionals or BOSLEYMD at 1(800)BOSLEY1

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May be harmful if used when pregnant or breast-feeding.



BOSLEY MD EXTRA STRENGTH FOR MEN minoxidil 5% solution **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:69113-002 **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength MINO XIDIL (UNII: 5965120 SH1) (MINO XIDIL - UNII:5965120 SH1) MINO XIDIL 5 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:69113-002-01	2 in 1 BOX	05/21/2020				
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	05/21/2020			

Labeler - Scientific Hair Research, LLC (961897647)

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