

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 different 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 immediately.

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

DIRECTIONS

- Apply one mL with dropper 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 health professional or BosleyMD at 1(800)BOSLEY1

MINOXIDIL LIQUID BOX FOR MEN 5% - 2 - 2.0 FL OZ/60ML - BOX

DOCUMENT INFORMATION	REVISION	VENDOR / PART#	FONTS	PMS	BOX COLOR	PRINTER INSTRUCTIONS	PLEASE NOTE
Client Name: Bosley Creation Date: 01/28/20 Final Art: Project Name: Bosley Minoxidil Liquid Box Mens File Name: BosleyMD_RegrowthTreatment_Mens_LiquidBox Rough <input type="checkbox"/> Comp <input type="checkbox"/> Mechanical <input checked="" type="checkbox"/>	R1: 01/28/20 R2: 02/14/20 R3: 02/20/20 R4: 02/25/20 R5: 02/24/20 R6: 02/28/20 R7: 03/19/20 R8: 04/08/20		All fonts converted to paths for printer	10272 C Cool Gray 11	White	Printable area 7.6563 x 12.5	COLORS ON SCREEN OR PRINTOUT MAY NOT BE REPRESENTATIVE. USE SWATCHBOOK. NO TRAPPING PROVIDED

3.0" 1.625" 3.0" 1.625" 5.875"

BOSLEY MD
EXTRA STRENGTH FOR MEN
MINOXIDIL TOPICAL SOLUTION 5%

Drug Facts

Active ingredient: Minoxidil 5% (Hair regrowth treatment)

Purpose: Use to regrow hair on the top of the scalp. Visible only. See picture on side of box.

Warnings: For external use only. For 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 box 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 falls out when you are angry
- 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, itchy, or painful
- you use other medications 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 or hair 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 seeing 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

Drug Facts (continued)

Warnings: (continued)

- swallow. Unintended weight gain occurs - your hands or feet swell
- scalp irritation or redness occurs
- swallow. Irritation to redness occurs
- you do not see hair regrowth in 4 months.

May be harmful if used when pregnant or breastfeeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions:

- sightly tilted, with a 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 box before use. Read all information on carton and enclosed insert
- keep carton. 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 18-49 years with moderate degrees of hair loss. Minoxidil Topical Solution 5% for men showed more hair regrowth than Minoxidil Topical Solution 2%.
- store at controlled room temperature 20° to 25° (68° to 77°)

Inactive ingredients: alcohol, propylene glycol, purified water

Questions or comments? call your health professional or BosleyMD at 1800BOSLEY1

BosleyMD Extra Strength for Men Hair Regrowth Treatment (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. BosleyMD Extra Strength for Men (minoxidil topical solution 5%) has been shown to regrow hair in men with the following degrees of thinning hair or hair loss. (See below).

If men have more hair loss or hair loss in a place different than shown below, BosleyMD Extra Strength for Men may not work.

NDC 49113-003-01

BOSLEY MD
Minoxidil
Topical Solution,
5% (For Men)
HAIR REGROWTH
TREATMENT

CLINICALLY PROVEN

Mess-Free,
Precise
Application

2 MONTH SUPPLY
2 - 60ML 2 FL. OZ. BOTTLES

VERTEX

VERTEX

VERTEX

NOT FOR USE BY WOMEN

NOT FOR USE BY WOMEN

THIS BOX CONTAINS TWO 60 mL (2 FL. OZ.) BOTTLES OF HAIR REGROWTH TREATMENT 5% FOR MEN ONE CHILD-RESISTANT DROPPER APPLICATOR READ ENCLOSED INSERT BEFORE USE

BP-SGF0004N HRTM02B-01

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BOSLEY MD EXTRA STRENGTH FOR MEN

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69113-003
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
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69113-003-01	2 in 1 BOX	05/21/2020	
1		2 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)

Revised: 4/2024

Scientific Hair Research, LLC