BOSLEY MINOXIDIL TOPICAL SOLUTION 5 (FOR MEN)- minoxidil liquid Scientific Hair Research, LLC

BOSLEY Minoxidil Topical Solution, 5% (for men)

Drug Facts

Active Ingredient

Minoxidil 5.0%w/v

Purpose

Hair Regrowth Treatment for Men

Use

to regrow hair on the top of the scalp (vertex 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 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 part of the body
- avoid contact with the eyes. in case of accidental contact, rinse eyes with large amount of cool tap water
- some people have experienced changes in hair colour 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 swaell
- 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 immediatly.

Directions

- apply one ml. (6 sprays) 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, it contains important information
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with Minoxidil Topical Solution 5% for men
- in clinical studies with mostly white men aged 18-45 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° (68° to 77°)

Inactive Ingredients

alcohol, propylene glycol, purified water

Questions or comments?

Call us at 1-800-267-5391 or visit website at www.bosleymd.com

Package Labelling:



BOSLEY MINOXIDIL TOPICAL SOLUTION 5 (FOR MEN)

minoxidil liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69113-483
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)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69113-483- 00	1 in 1 BOX	05/06/2024			
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	05/06/2024		

Labeler - Scientific Hair Research, LLC (961897647)

Revised: 5/2024 Scientific Hair Research, LLC