MINOXIDIL (FOR MEN)- minoxidil aerosol, foam SCIENTIFIC HAIR RESEARCH, LLC

Minoxidil (for Men)

Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)

Warnings

For external use only.

For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical foam 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 dosage. 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 half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- 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.
- store at controlled room temperature 20° to 25°C (68° to 77°F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Inactive ingredients

butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

• Call 1-866-923-4914

Distributed by: BosleyMD

PRINCIPAL DISPLAY PANEL - 60 G Can Package

NDC 69113-128-01

BOSLEY MD®

*Compare to the active ingredient of Men's Rogaine®

#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT[†] NOT FOR USE BY WOMEN

EASY-TO-USE FOAM FOR MEN

MINOXIDIL TOPICAL AEROSOL 5% (FOR MEN)

HAIR REGROWTH TREATMENT

UNSCENTED

REVITALIZES HAIR FOLLICLES

CLINICALLY PROVEN TO HELP REGROW HAIR

ONE MONTH SUPPLY ONE 60 G (2.11 OZ) CAN



671 2214286-1220-1

NDC 69113-128-01 BOSLEYMD MINOXIDIL TOPICAL **AEROSOL 5%** (FOR MEN) HAIR REGROWTH TREATMENT UNSCENTED EASY-TO-USE FOAM FOR MEN

Drug Facts

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Warnings

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For use by men only. Extremely Flammable: Avoid fire, flame, or smoking during and immediately following

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- 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
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 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

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Other information

hair growth has been shown in a clinical study of men (mostly white) aged 18-49

Drug Facts

(continued)

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- contents under pressure. Do not puncture or incinerate container. Do not expose to heat o store at temperatures above 120°F (49°C).

Inactive ingredients

butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

Call 1-800-BOSLEY1 (1-800-267-5391)

Minoxidil Topical Aerosol, 5% (For Men) 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

Minoxidil Topical Aerosol, 5% (For Men) has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.







VERTEX



If men have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Aerosol, 5% (For Men) may not work. NDC 69113-128-01

Men's Rogaine

#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT

NOT FOR USE BY WOMEN

EASY-TO-USE FOAM



MINOXIDIL TOPICAL AEROSOL 5% (FOR MEN)

HAIR REGROWTH TREATMENT

UNSCENTED

REVITALIZES HAIR FOLLICLES

CLINICALLY PROVEN TO HELP **REGROW HAIR**

ONE MONTH SUPPLY ONE 60 G (2.11 OZ) CAN

THIS PACKAGE CONTAINS

One 60 g (2.11 oz) can of Minoxidil Topical
Aerosol, 5% (For Men) (one month supply)

USING THE PRODUCT

- · To open: Match arrow on can ring with arrow on cap. Pull off cap.
- · Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
- . The foam may begin to melt right away on contact with your warm skin, If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam.)
- · Hold the can straight upside down and press nozzle to dispense the topical foam product onto your fingers. The total amount of foam applied should not exceed half a capful.
- . Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
- · After each use, close the container to make child resistant by snapping the cap back on to the can.





OPEN CONTAINER

PART THE HAIR





HOLD CAN STRAIGHT

USE YOUR FINGERS

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Men's Rogaine®.

Made in Israel Distributed by: BosleyMD

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In the U.S. Source: AlphalmpactRx

BP-SGF0035N



NOT FOR USE BY WOMEN

MINOXIDIL (FOR MEN)

minoxidil aerosol, foam

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69113-128

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
Minoxidil (UNII: 5965120 SH1) (Minoxidil - UNII:5965120 SH1)	Minoxidil	50 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
butylated hydroxytoluene (UNII: 1P9 D0 Z171K)		
cetyl alcohol (UNII: 936JST6JCN)		
anhydrous citric acid (UNII: XF417D3PSL)		
alcohol (UNII: 3K9958V90M)		
isobutane (UNII: BXR49TP611)		
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)		
butane (UNII: 6LV4FOR43R)		
polysorbate 60 (UNII: CAL22UVI4M)		
propane (UNII: T75W9911L6)		
water (UNII: 059QF0KO0R)		
stearyl alcohol (UNII: 2KR89I4H1Y)		

Product Characteristics			
Color	WHITE (white to off-white foam)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69113-128-01	1 in 1 PACKAGE	12/23/2020	
1		60 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:69113-128-03	3 in 1 PACKAGE	12/23/2020	
2		60 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209074	12/23/2020	

Labeler - SCIENTIFIC HAIR RESEARCH, LLC (961897647)

Revised: 1/2021 SCIENTIFIC HAIR RESEARCH, LLC