

MINOXIDIL- minoxidil aerosol, foam
P & L Development, LLC

Minoxidil Topical Solution for Men

Drug Facts

Active ingredient

Minoxidil 5% w/v (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 carton)

Warnings

For external use only. For use by men only.

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 the side of this carton or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% (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 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 and pets

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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 clinical study of men (mostly white) aged 18-49 years who used it for 4 month
- 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

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

Questions?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel

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

men's hair regrowth treatment

minoxidil topical aerosol, 5%

hair regrowth treatment

- clinically proven to help regrow hair
- reactivates hair follicles to stimulate regrowth
- unscented

easy-to-use foam

NOT FOR USE BY WOMEN

THREE MONTH SUPPLY

THREE 60 G (2.11 OZ) CANS

g (FL OZ) cans

Read and keep carton and information leaflet for full product information.

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Men's Rogaine®.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Package label

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- 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, itchy, dandruff, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have heart disease

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- Do not expose to heat or store at temperatures above 120° F (49° C).

Inactive Ingredients sulfate, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polyisobutene, propellant, purified water, SD alcohol 40-1, stearic alcohol

Questions? Call 1-877-753-3838 Monday-Friday 9AM-5PM EST

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THIS PACKAGE CONTAINS

- Three 60 g (2.11 oz) cans of Minoxidil Topical Aerosol, 5% (Foam) (three month supply)

DIRECTIONS FOR USE

See information leaflet with complete directions on how to use and obtain best results.

- 1. PREP HANDS WITH COLD WATER**
Wet your fingers in cold water and dry them. Hair loss will melt on contact with warm surfaces.
- 2. OPEN CHILD RESISTANT CAP**
Do not touch the tip of the cap with your finger. Hold the cap with thumb and index finger. Turn the cap back and pull off.
- 3. DISPENSE VERTICALLY ONTO A COLD SURFACE**
Hold the can straight upside down. If you hold the can at an angle, foam may not dispense properly. Press nozzle to dispense a half a capful of foam onto a cold surface (e.g. dish, or cold towel).
- 4. APPLY TO SCALP, NOT HAIR**
Part your hair to expose the hair loss area. Massage foam into scalp, not hair. Repeat until all hair loss areas have been covered.
- 5. CLOSE CAP AND WASH HANDS**
Snap cap back into place. Do not touch the tip of the cap. Do not touch the nozzle. Wash hands and any surface thoroughly after use.

For best results: Use twice daily. Apply directly to the scalp.

Read and keep carton and information leaflet for full product information.

PLD-07988 F000768 Product of Italy

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Wellness Basics - Minoxidil_ment (6.33 oz - Pack of 3)
New

WELLNESS BASICS Men's hair regrowth treatment

MINOXIDIL

minoxidil aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-125
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
BUTANE (UNII: 6LV4FOR43R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID (UNII: 33X04XA5AT)	

POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-125-60	1 in 1 PACKAGE	10/01/2023	
1		60 mL in 1 CAN; Type 0: Not a Combination Product		
2	NDC:59726-125-70	3 in 1 PACKAGE	10/01/2023	
2		60 mL 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	ANDA208092	10/01/2023	

Labeler - P & L Development, LLC (800014821)