

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

Minoxidil Topical Solution 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 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 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.

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 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 temperature 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 active ingredient in Men's Rogaine®

Men's

Hair Regrowth Treatment

Minoxidil Topical Aerosol, 5%

- Clinically proven to help regrow hair
- Reactivates hair follicles to stimulate regrowth
- Unscented

EASY-TO-USE FOAM

Not For Use By Women

1 CAN

60 g (2.11OZ CAN)

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

Package label

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
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Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.
Do not use if
 • you are a woman
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 • you have no family history of hair loss
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 • you do not know the reason for your hair loss
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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
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 • chest pain, rapid heartbeat, faintness, or dizziness occurs
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 • 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 (1-800-222-1222) right away.

Directions
 • apply half a can (1/2 times a day) to the scalp in the hair loss area
 • massage into scalp with fingers. Then wash hands well
 • use 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 incise the container.
 • Do not expose to heat or store at temperatures above 120° F (49° C).

Inactive ingredients Isotane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polyacrylate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

Questions? Call 1-877-763-3806 Monday-Friday 9AM-5PM EST

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THIS PACKAGE CONTAINS
 • One 60 g (2.11 oz) can of Minoxidil Topical Aerosol, 5% (foam) (one 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
 Rinse your fingers in cold water and dry them. **Note:** Fingers will wet on contact with warm surfaces.

2. OPEN CHILD RESISTANT CAP
 Be sure to align arrow on the cap with arrow on white top. Flip 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 half a canful of foam onto a cold surface (e.g. dish, or cold hands).

4. APPLY TO SCALP, NOT HAIR
 Part your hair to expose hair loss areas. 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. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.

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

Vertex (with diagrams of hair loss areas on the scalp)

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

If men have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Aerosol, 5% (foam) may not work.

NDC 59726-115-60
 *Compare to the active ingredient in Men's Rogaine®

Men's Hair Regrowth Treatment

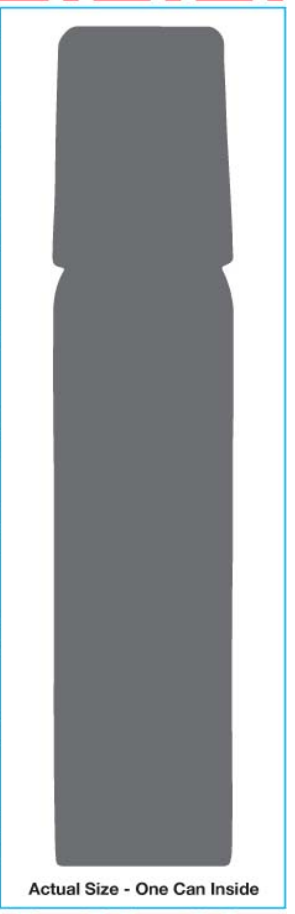
Minoxidil Topical Aerosol, 5%

- ✓ Clinically proven to help regrow hair
- ✓ Reactivates hair follicles to stimulate regrowth
- ✓ Unscented

EASY-TO-USE FOAM

Not For Use By Women

ONE MONTH SUPPLY - One 60 g (2.11 oz) Can



PLD-A718A F008622

Lot No.:
Exp. Date:

Men's Hair Regrowth Treatment

MINOXIDIL			
minoxidil aerosol, foam			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-115
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 g	
Inactive Ingredients			

Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-115-60	60 g in 1 CAN; Type 0: Not a Combination Product	05/05/2023	
2	NDC:59726-115-70	3 in 1 PACKAGE	05/05/2023	
2		60 g in 1 CAN; Type 0: Not a Combination Product		
3	NDC:59726-115-65	2 in 1 PACKAGE	05/05/2023	
3		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	ANDA208092	05/05/2023	

Labeler - P & L Development, LLC (800014821)

Revised: 5/2023

P & L Development, LLC