

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 women

Use

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

Warnings

For external use only.

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

Do not use if

- your degree of hair loss is different than that shown on the side of this carton because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- 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 use more than directed
- 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 3 months with **once daily** use For some women, you may need to use this product **once a day** for at least 6 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 6 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

- see enclosed leaflet for complete directions on how to use
- apply half a capful **once daily** directly to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- 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 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-Bstearyl alcohol

Questions?

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

Principal display panel

†Compare to active ingredient in Women's Rogaine®

women's

minoxidil topical aerosol, 5%

hair regrowth treatment

once-a-day

foam for women

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

60 g (2.11OZ CAN)

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 Women's Rogaine®.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package label

Drug Facts

Active Ingredient Minoxidil 5% w/w (without propellant) **Purpose** Hair regrowth treatment for women

Use To regrow hair on the top of the scalp (see pictures on side of this carton)

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 • you use other medicines on the scalp
 Ask a doctor before use if you have heart disease

When using this product
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 • 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 3 months with once-daily use. For some women, you may need to use this product once a day for at least 6 months before you see results.
 • the amount of hair regrowth is different for each person. This product will not work for all women.

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 6 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
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 • massage into scalp with fingers, then wash hands well
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 • continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

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Inactive ingredients butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polyborate 60, propane, purified water, SD alcohol 40-8, stearyl alcohol

Questions? Call 1-877-783-3838 Monday-Friday 9AM-5PM EST

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Distributed by:
PL Developments
 200 Hicks Street
 Westbury, NY 11590

THIS PACKAGE CONTAINS
 • One 60 g (2.11 oz) can of Minoxidil Topical Aerosol, 5% (Foam) (two month supply)

Minoxidil Topical Aerosol, 5% is for women who have a general thinning of hair on the top of the scalp (as shown below) and has been shown to regrow hair in women with the following degrees of thinning hair or hair loss.

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. Water foam will melt on contact with warm surfaces.
 - 2: OPEN CHILD RESISTANT CAP**
 Be sure to align arrow on the cap with arrow on white ring. Till 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 capful 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 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. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.

If women have more hair loss than shown above, Minoxidil Topical Aerosol, 5% (For Women) may not work.

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



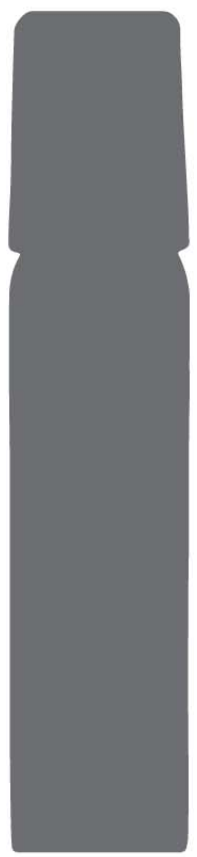
†Compare to the active ingredient in Women's Rogaine®
 NDC 59726-122-60



once-a-day foam for women

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

two month supply - one 60 g (2.11 oz) can



actual size - one can inside



Lot No.:
 Exp. Date:

READYinCASE Hair Regrowth Treatment

MINOXIDIL			
minoxidil aerosol, foam			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-122
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:59726-122-60	1 in 1 PACKAGE	05/31/2024	
1		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	05/31/2024	

Labeler - P & L Development, LLC (800014821)

Revised: 5/2024

P & L Development, LLC