

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

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**Minoxidil Topical Solution for Men**

***Drug Facts***

***Active ingredient***

Minoxidil, USP 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 regrowth, or hair loss will begin again

***Other information***

- hair regrowth has been shown in a 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 room 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 minoxidil Topical aerosol, 5%,

hair regrowth treatment

easy-to-use foam

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

## **not for use by women**

g (oz) 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 Rogaine®.

Distributed by:

## **PL Developments**

200 Hicks Street

Westbury, NY 11590

## **Package label**

<b>Drug Facts</b>	
<b>Active ingredient</b> Minoxidil 5% w/w (without propellant)	<b>Purpose</b> Hair regrowth treatment for men
<b>Use</b> - to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)	
<b>Warnings</b> For external use only. For use by men only. Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application. <b>Do not use if</b> <ul style="list-style-type: none"> <li>you are a woman</li> <li>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.</li> <li>you have no family history of hair loss</li> <li>your hair loss is sudden and/or patchy</li> <li>you do not know the reason for your hair loss</li> <li>you are under 18 years of age. Do not use on babies and children.</li> <li>your scalp is red, inflamed, infected, irritated, or painful</li> <li>you use other medicines on the scalp</li> </ul> <b>Ask a doctor before use if you have heart disease</b> <b>When using this product</b> <ul style="list-style-type: none"> <li>do not apply on other parts of the body</li> <li>avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.</li> <li>some people have experienced changes in hair color and/or texture</li> <li>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.</li> <li>the amount of hair regrowth is different for each person. This product will not work for all men.</li> </ul> <b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>chest pain, rapid heartbeat, faintness, or dizziness occurs</li> <li>sudden, unexplained weight gain occurs</li> <li>your hands or feet swell</li> <li>scalp irritation or redness occurs</li> <li>unexpected facial hair growth occurs</li> <li>you do not see hair regrowth in 4 months</li> </ul> <b>May be harmful if used when pregnant or breast-feeding.</b> <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>apply half a capful 2 times a day to the scalp in the hair loss area</li> <li>massage into scalp with fingers, then wash hands well</li> <li>see enclosed leaflet for complete directions on how to use</li> <li>using more or more often will not improve results</li> <li>continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>hair growth has been shown in a clinical study of men (mostly white) aged 18 - 49 years who used it for 4 months</li> <li>see hair loss pictures on side of this carton</li> <li>before use, read all information on carton and enclosed leaflet</li> <li>keep the carton. It contains important information.</li> <li>store at controlled room temperature 20° to 25° C (68° to 77° F)</li> <li>contents under pressure. Do not puncture or incinerate container.</li> <li>Do not expose to heat or store at temperatures above 120° F (49° C).</li> </ul>	
<b>Inactive ingredients</b> butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polyvinylate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol	
<b>Questions?</b> call 1-877-753-8835 Monday-Friday 9AM-5PM EST	

\*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

**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:** foam will melt on contact with warm surfaces.



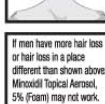
**2: OPEN CHILD RESISTANT CAP**  
 Be sure to align arrow on the cap with arrow on white ring. Tilt cap back and pull out.



**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.

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

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

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

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



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

NDC 59726-151-60

men's  
 minoxidil  
 topical  
 aerosol,  
 5%  
 hair regrowth treatment

easy-to-use  
 foam

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

**not for use by women**

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

actual size - one can inside



Lot No:  
 Exp. Date:

## READYinCASE Hair Regrowth Treatment for Men's

### MINOXIDIL

minoxidil aerosol, foam

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-151
<b>Route of Administration</b>	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
<b>BUTANE</b> (UNII: 6LV4FOR43R)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPANE</b> (UNII: T75W9911L6)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-151-60	1 in 1 PACKAGE	07/01/2024	
1		60 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:59726-151-70	3 in 1 PACKAGE	07/01/2024	
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	ANDA208092	07/01/2024	

**Labeler - P & L Development, LLC (800014821)**