

**MINOXIDIL- minoxidil aerosol, foam**  
**Hims Inc.**

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**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 this carton)

***Warnings***

**For external use 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
- 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 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) ages 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 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 **1-800-368-0038**

### **Principal display panel**

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

Men's

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

ONE MONTH SUPPLY

60 g (2.11OZ) CAN

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

Distributed by Hims, Inc.,

2269 Chestnut St #523, San Francisco, CA 94123

### **Package label**

**Drug Facts**

**Active ingredient** Minoxidil 5% w/v (with but 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 it**  
 • 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  
 • you breathe or feel 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 temperatures above 120° F (49° C).  
**Inactive ingredients** butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polybutene 60, propene, purified water, SD alcohol 40-B, stearyl alcohol  
**Questions? 1-800-368-0030**  
\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Men's Rogaine®.  
 Distributed by Hims, Inc., 2269 Chestnut St #521, San Francisco, CA 94122

NDC XXXXX-XXX-XX

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

# Men's Minoxidil Topical Aerosol, 5%

## Hair Regrowth Treatment

6.818  
[173.18]

✓ 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

**DIRECTIONS FOR USE**

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

- PREP HANDS WITH COLD WATER**  
 Raise your fingers in cold water and dry them. **NOTE:** foam will not be in contact with warm surfaces.
- OPEN CHILD RESISTANT CAP**  
 Be sure to align arrow on the cap with arrow on white ring. Tilt cap back and pull off.
- 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 hand).
- 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.
- 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% (Foam) 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.

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

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

### HIMS 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:71730-115
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 g
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### 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:71730-115-01	1 in 1 PACKAGE	06/30/2024	
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	06/30/2024	

**Labeler** - Hims Inc. (080678637)

Revised: 4/2024

Hims Inc.