

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

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**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

Hair Regrowth Treatment

Minoxidil Topical Aerosol, 5%

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

## **Once-a Day**

Foam for women

60 g (2.11OZ CAN)

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

## **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)

**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 children
- 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
- women 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, dizziness, 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
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**Other information**

- see hair loss pictures on side of the carton
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- keep the carton. It contains important information.
- store at controlled room temperature 20° to 25° C (68° to 77° F)
- contains 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, polypropylene 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

**Questions?** Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

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

**THIS PACKAGE CONTAINS**

- One 60 g (2.11 oz) can of Minoxidil Topical Aerosol, 5% (Foam) (Two 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 meet on contact with warm surfaces.

**2: OPEN CHILD RESISTANT CAP**  
 Be sure to align arrow on the cap with arrow on white ring. Lift 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 hand).

**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 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.**



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


NDC 59726-116-60  
 \*Compare to the active ingredient in Women's Rogaine®

# Women's Hair Regrowth Treatment


## Minoxidil Topical Aerosol, 5%

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

**Once-a-Day Foam for Women**




**TWO MONTH SUPPLY - One 60 g (2.11 oz) Can**



**Actual Size - One Can Inside**

PLD-A799A F000825



Lot No.:  
 Exp. Date:

## Women's Hair Regrowth Treatment

<b>MINOXIDIL</b>			
minoxidil aerosol, foam			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-116
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 g
<b>Inactive Ingredients</b>			

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)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-116-60	60 g in 1 CAN; Type 0: Not a Combination Product	05/05/2023	
2	NDC:59726-116-65	2 in 1 PACKAGE	05/05/2023	
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	05/05/2023	

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

Revised: 5/2023

P & L Development, LLC