MINOXIDIL- minoxidil aerosol, foam Profectus Beauty, 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 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

- 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-B, stearyl alcohol

Questions?

Call toll free 1-888-237-4131

Principal display panel

*Compare to active ingredient in Women's Rogaine®

Minoxidil

Topical Aerosol, 5%

Hair Regrowth Treatment For Women

Clinically proven to help regrow hair

Reactivates hair follicles to stimulate regrowth

Unscented

Once-a Day

Foam for women

TWO MONTH SUPPLY

60 g (2.110Z CAN

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

Distributed by:

Profectus Beauty, LLC.,

111 Town Square Pl, Suite 1130

Jersey City, NJ 07310

Package label



KERANIQUE Hair Regrowth Treatment For Women

MINOXIDIL minoxidil aerosol, foam Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Basis of Strength	Strength
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				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:70550-116- 02	1 in 1 PACKAGE	03/15/2024				
1		60 g in 1 CAN; Type 0: Not a Combination Product					
2	NDC:70550-116- 20	2 in 1 PACKAGE	03/15/2024				
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	03/15/2024			

Labeler - Profectus Beauty, LLC (118310694)

Revised: 3/2024 Profectus Beauty, LLC