MINOXIDIL (FOR MEN)- minoxidil aerosol, foam RESTORATION HOLDINGS, LLC

Minoxidil 5% w/w (without propellant)

Hair regrowth treatment for men

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 side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical 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 right away. (1-800-222-1222)

- 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
- 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).

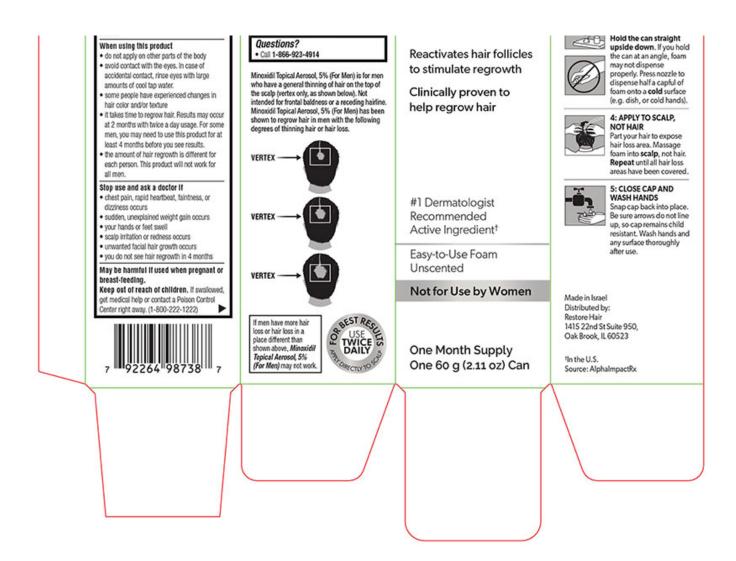
butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

Call 1-866-923-4914

Keep out of reach of children

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





MINOXIDIL (FOR MEN)

minoxidil aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82796-100
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	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
BUTANE (UNII: 6LV4FOR43R)		
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)		
ISOBUTANE (UNII: BXR49TP611)		

ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPANE (UNII: T75W9911L6)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Product Characteristics			
Color	white (white to off-white foam)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82796-100- 01	1 in 1 BOX	01/01/2023	
1		60 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209074	01/01/2023	

Labeler - RESTORATION HOLDINGS, LLC (015481069)

Registrant - Taro Pharmaceutical (173762329)

Revised: 12/2023 RESTORATION HOLDINGS, LLC