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

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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).

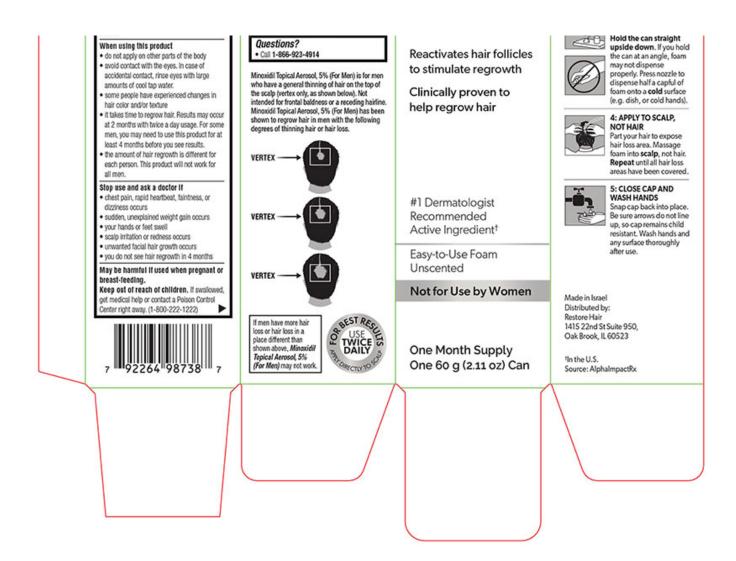
butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

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: 12/2024 RESTORATION HOLDINGS, LLC