

MINOXIDIL 5% (FOR MEN)- minoxidil aerosol, foam
Taro Pharmaceuticals U.S.A., Inc.

Minoxidil
5% (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.

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)

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

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

Questions?

- Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 60 g Can Package

*Compare to the active
ingredient of
Men's Rogaine®

NDC 51672-2128-4

Minoxidil
Topical Aerosol,
5% (For Men)

HAIR REGROWTH
TREATMENT

REACTIVATES
HAIR FOLLICLES
TO STIMULATE
REGROWTH

CLINICALLY
PROVEN TO HELP
REGROW HAIR

Easy-to-use
foam

UNSCENTED

#1 DERMATOLOGIST
RECOMMENDED
ACTIVE INGREDIENT†

Not For Use By Women

One Month Supply
One 60 g (2.11 oz) Can



911
5200760-0521-4

NDC 51672-2128-4

Minoxidil Topical Aerosol, 5% (For Men)



Easy-to-use
foam

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Drug Facts (continued)

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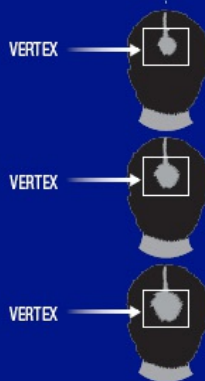
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Minoxidil Topical Aerosol, 5% (For Men) is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil Topical Aerosol, 5% (For Men) has been 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% (For Men)** may not work.



THIS PACKAGE CONTAINS

- One 60 g (2.11 oz) can of Minoxidil Topical Aerosol, 5% (For Men) (one 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 melt on contact with warm surfaces.



2: OPEN CHILD RESISTANT CAP

Be sure to align arrow on the cap with arrow on white ring. Tilt 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 hands).



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.

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Men's Rogaine®.



Made in Israel
Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.

†In the U.S.
Source: AlphaImpactRx

MINOXIDIL 5% (FOR MEN)

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2128
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)	
cetyl alcohol (UNII: 936JST6JCN)	
anhydrous citric acid (UNII: XF417D3PSL)	
alcohol (UNII: 3K9958V90M)	
isobutane (UNII: BXR49TP611)	
lactic acid, unspecified form (UNII: 33X04XA5AT)	
butane (UNII: 6LV4FOR43R)	
polysorbate 60 (UNII: CAL22UVI4M)	
propane (UNII: T75W9911L6)	
water (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:51672-2128-4	1 in 1 PACKAGE	01/02/2019	
1		60 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:51672-2128-9	3 in 1 PACKAGE	01/02/2019	
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	ANDA209074	01/02/2019	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-2128)

Revised: 6/2021

Taro Pharmaceuticals U.S.A., Inc.