

MENS MINOXIDIL HAIR GROWTH SYSTEM- minoxidil solution
Topiderm, Inc.

Men's Minoxidil
Hair Growth System

Drug Facts

Active Ingredient

Minoxidil 5% w/v

Purpose

Hair Regrowth for men

Warnings

For external use only. For use by men only.

Flammable: Keep away from fire or flame

Use

To regrow hair on the scalp

Do not use if

- you are a woman
- 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 or 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

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

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

Directions

Apply one mL 2 times a day directly onto the scalp in the hair loss area

- see enclosed leaflet for complete Directions for Use
- using more or more often will not improve result
- continued use is necessary, or hair loss will begin again

Inactive Ingredients

Alcohol, Propylene Glycol, Purified Water

Questions?

Call Topiderm at 800-445-2595 or reach us on the internet at topiderm.com

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

Distributed By: Topiderm Inc., 5200 New Horizons Blvd. N. Amityville, NY 11701

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

COMPLIMENTS OF
TOPIX
PHARMACEUTICALS, INC

MEN'S
Minoxidil Hair Regrowth

EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION, USP
HAIR REGROWTH TREATMENT

Reactivates Hair Follicles to Stimulate Regrowth
Clinically Proven to Help Regrow Hair
Topical Solution
Unscented

For Best Results:
Apply Directly to Scalp. Use Twice Daily

One Month Supply 60mL (2 fl oz)

Available Custom Branded
800.445.2595

NDC XX-XX-XX

Read and keep carton and leaflet for full product information

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c.service@topixpharm.com

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1060 Made in the U.S.A R0421

MENS MINOXIDIL HAIR GROWTH SYSTEM

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-160
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 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-160-16	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	03/23/2021	

Labeler - Topiderm, Inc. (049121643)**Establishment**

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals Inc		613171433	PACK(51326-160)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	MANUFACTURE(51326-160)

Revised: 4/2021

Topiderm, Inc.