

MINOXIDIL TOPICAL SOLUTION, 5%- minoxidil solution solution
Sun Pharmaceutical Industries, Inc.

Minoxidil Topical Solution USP, 5%

Drug Facts

Active ingredient

Minoxidil USP 5% w/v

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.

Flammable: Keep away from fire or flame

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution 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 one mL with dropper 2 times a day directly onto the scalp in the hair loss area
- 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.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men
- In clinical studies with mostly white men aged 18 to 49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- store at controlled room temperature 20° to 25° C (68° to 77° F)

Inactive ingredients

alcohol (28.86% v/v), propylene glycol, purified water

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Made in Israel

Questions?

Call toll-free **1-866-923-4914**

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

NDC 51672-2151-4

One 60 mL (2 fl oz)

87
5240474-0225-00

Men's Extra Strength
**Minoxidil
Topical Solution
USP, 5%**
HAIR REGROWTH TREATMENT


**Topical
Solution**

NDC 51672-2151-4

ohm
LABORATORIES INC.
a SUN PHARMA company

Men's Extra Strength
**Minoxidil
Topical Solution
USP, 5%**


**Topical
Solution**

HAIR REGROWTH
TREATMENT

REACTIVATES
HAIR FOLLICLES
TO STIMULATE
REGROWTH

CLINICALLY
PROVEN TO HELP
REGROW HAIR

UNSCENTED

Not For Use
By Women


One Month Supply
One 60 mL (2 fl oz) Bottle

**#1 DERMATOLOGIST
RECOMMENDED
ACTIVE INGREDIENT***

THIS PACKAGE CONTAINS



- One 60 mL (2 fl oz)
Bottle of **Men's Minoxidil
Topical Solution USP, 5%
Extra Strength** (one month
supply)
- One child-resistant dropper
applicator
- Information leaflet with
complete directions on how
to use and obtain best
results

*OHM and OHM Logo are trademarks of
Ohm Laboratories, Inc. All other trademarks
are the property of their respective owners.

†In the U.S.
Source: Alphametric®

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
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Drug Facts (continued)

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Men's Minoxidil Topical Solution USP 5% Extra Strength 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.

Men's Minoxidil Topical Solution USP 5% Extra Strength has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

VERTEX

VERTEX

VERTEX



**FOR BEST RESULTS
USE
TWICE
DAILY
DIRECTLY TO SCALP**

If men have more hair loss or hair loss in a place different than shown above, Men's Minoxidil Topical Solution USP 5% Extra Strength may not work.

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THIS FLAP FOR LOT #
AND EXP DATE PRINT

MINOXIDIL TOPICAL SOLUTION, 5%

minoxidil solution solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2151
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
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2151-4	1 in 1 CARTON	08/01/2025	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:51672-2151-9	3 in 1 CARTON	08/01/2025	
2		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217998	08/01/2025	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	manufacture(51672-2151)

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.