MINOXIDIL TOPICAL SOLUTION 2%- minoxidil topical solution 2% solution SUN PHARMACEUTICAL INDUSTRIES, INC.

Drug Facts

Active ingredient

Minoxidil USP 2% w/v

Purpose

Hair regrowth treatment

Use

to regrow hair on the scalp

Warnings

For external use only.

Flammable: Keep away from fire or flame

Do not use if

- your degree of hair loss is different than that shown on the side of this carton, because this product may not work for you
- · you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- 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. You may need to use this product 2 times a day 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 everyone

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.
- In clinical studies of mostly white women aged 18 to 45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- store at controlled room temperature 20° to 25° C (68° to 77° F)

Inactive ingredients

alcohol (59.85% v/v), propylene glycol, purified water

Questions?

Call toll-free 1-866-923-4914

Package/Label Principal Display Panel

NDC 51672-2152-4

Women's Minoxidil Topical Solution USP, 2%

HAIR REGROWTH TREATMENT

REACTIVATES HAIR FOLLICLES TO STIMULATE REGROWTH

CLINICALLY PROVEN TO HELP REGROW HAIR

UNSCENTED

One Month Supply

One 60 mL (2 fl oz) Bottle



MINOXIDIL TOPICAL SOLUTION 2%

minoxidil topical solution 2% solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2152	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 mg in 1 mL	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672- 2152-4	1 in 1 CARTON	09/01/2025	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672- 2152-9	3 in 1 CARTON	09/01/2025	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA218175	09/01/2025		

Labeler - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceutical Industries Ltd.		600072078	manufacture(51672-2152)	

Revised: 10/2024 SUN PHARMACEUTICAL INDUSTRIES, INC.