NIOXIN HAIR REGROWTH TREATMENT EXTRA STRENGTH FOR MENminoxidil solution The Wella Corporation

Nioxin Hair Regrowth Treatment Extra Strength for Men Drug Facts

Active ingredient

Minoxidil 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 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. Minoxidil topical solution 5% 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 minoxidil topical solution 5% for men
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%
- store at 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients

alcohol, propylene glycol, purified water

Questions?

Call 1-800-719-9260

MADE IN CANADA

Dist. By THE WELLA CORPORATION, WOODLAND HILLS, CA 91367

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

NIOXIN®

MINOXIDIL

TOPICAL SOLUTION USP 5%

HAIR REGROWTH TREATMENT

EXTRA STRENGTH FOR MEN

Clinically Proven To Help Regrow Hair Reactivates Hair Follicles To Stimulate Regrowth

NOT FOR USE BY WOMEN

ONE MONTH SUPPLY FDA APPROVED

1-60 mL (2 fl oz) Bottle UNSCENTED



NIOXIN HAIR REGROWTH TREATMENT EXTRA STRENGTH FOR MEN

minoxidil solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69282-002

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

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

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:69282- 002-60	1 in 1 CARTON	11/01/2014				
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product					
2	NDC:69282- 002-18	3 in 1 CARTON	11/01/2014				
2		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075598	11/01/2014		

Labeler - The Wella Corporation (001399815)

Revised: 10/2023 The Wella Corporation