

KEEPS- minoxidil 5% liquid
Thirty Madison Inc

Minoxidil 5.0% w/v

Hair regrowth treatment for men

to regrow hair on the scalp (vertex only, see picture on side of carton)

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, 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.

- 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
- 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 of mostly white men aged 18-49 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).

Alcohol, Propylene Glycol, Purified Water

Questions or comments?
1-833-745-3377

Drug Facts	
Active ingredient Minoxidil 5% w/v	Purpose Hair regrowth treatment for men
Use To regrow hair on the scalp. (For use only, see picture on side of carton.)	
Warnings For external use only. For use by men only. Phenylethylamine may cause dizziness or drowsiness. 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, itchy 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.	
May see and ask a doctor if: - chest pain, rapid heartbeat, hairiness, 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. 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 picture 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 of mostly white men aged 18-49 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, Propylene Glycol, Purified Water Questions or comments? 1-833-745-3377	

THIS PACKAGE CONTAINS

Three 60 mL (2 fl oz) bottles of Minoxidil topical solution 5% (Three month supply)

One child-resistant dropper applicator

Information leaflet with complete directions on how to use and obtain best results (Read enclosed leaflet before use)

Keeps

5% Minoxidil Topical Solution, USP

Men's Extra Strength Hair Regrowth Treatment

Reactivates Hair Follicles To Stimulate Regrowth

Clinically Proven To Help Regrow Hair

Topical Solution Unscented

NOT FOR USE BY WOMEN

FDA APPROVED

NDC 71713-095-10

Minoxidil Topical Solution 5% 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 Solution 5% has been shown to regrow hair in men with the following degrees of thinning or hair loss.

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

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

KEEPS

minoxidil 5% liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71713-095
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: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71713-095-	3 in 1 BOX	11/15/2017	

1	10	3 in 1 BOX	11/15/2017	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA074588		11/15/2017	

Labeler - Thirty Madison Inc (080774087)

Revised: 12/2017

Thirty Madison Inc