# GETTIK HAIR REGROWTH TREATMENT- minoxidil 5% liquid GETTIK International LLC

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Minoxidil 5.0% w/v

Hair regrowth treatment for men

To regrow hair on the top of the scalp (vertex only, see pictures 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. 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.

- apply one ML 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 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 growth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with Minoxidil Topical Solution 5%
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% provided more hair regrowth than Minoxidil Topical Solutions 2%
- store at controlled room temperature 20 degree to 25 degree C (68 degree to 77 degree F)

alcohol 30% v/v, propylene glycol 50% v/v, purified water

Questions: Call your health care professional or Gettik at 1-800-249-8095 or visit our website at https://gettik.com



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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)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71700- 112-05	3 in 1 BOX	10/01/2017			
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:71700- 112-03	1 in 1 BOX	10/01/2017			
2		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	10/01/2017		

# Labeler - GETTIK International LLC (080820486)

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