

**HAIR REGROW- 5% minoxidil topical solution solution**  
**Bentley Laboratories, LLC**

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**Men's Extra Strength Hair Regrow**

**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. 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 part of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some individuals (people) have experienced changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with 2 times daily usage of this product. 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
- you get unwanted facial hair growth
- 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 pictures on side of this carton
- before use, read all information on carton and enclosed booklet.
- 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 solutions for men.
- In clinical studies with 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?**

- 1-866-270-HAIR (4247)

9 am to 2 pm weekdays EST

- Visit [www.MyHairRegrow.com](http://www.MyHairRegrow.com)

**Men's Extra Strength HAIR Regrow**

Help regrow your hair with confidence

5% Minoxidil Topical Solution

Hair Regrowth Treatment

Unscented

Extra Strength Formula

Reactivates hair follicles to stimulate regrowth

Minoxidil is clinically proven to help regrow hair

Compare to Men's Rogaine<sup>®</sup> Active Ingredient\*

Not for use by women

30 day supply / 1-60 mL (2 fl oz) bottle



HAIR REGROW			
5% minoxidil topical solution solution			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54111-205
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)		<b>MINOXIDIL</b>	50 mg in 1 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54111-205-60	1 in 1 CARTON	08/24/2004	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA		ANDA076239	08/24/2004	

**Labeler** - Bentley Laboratories, LLC (068351753)

### Establishment

Name	Address	ID/FEI	Business Operations
Ei LLC		105803274	analysis(54111-205) , manufacture(54111-205)

Revised: 1/2018

Bentley Laboratories, LLC