# BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT REGULAR STRENGTH FOR MEN- minoxidil liquid

Pure Source, LLC

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### **Active Ingredient**

Minoxidil 5.0% w/v

#### **Purpose**

Hair regrowth treatment for men

#### Use

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

#### **Warnings**

For external use only

Flammable: keep away from fire or flame

#### Do not use if

- vou are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss 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 medications 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. Result may occur all 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 feel 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 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

#### 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 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)

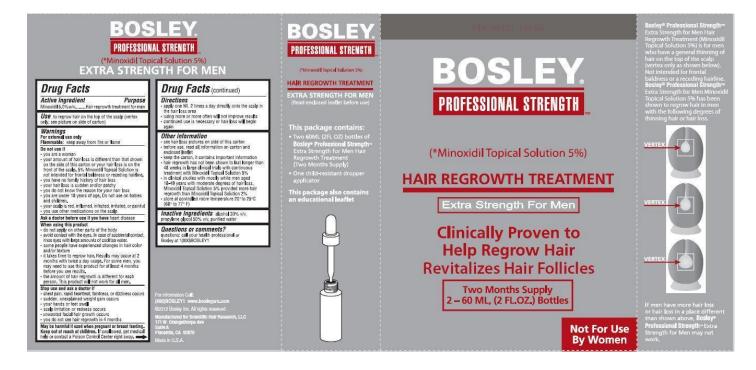
### **Inactive ingredients**

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

#### Questions or comments?

questions: call your health professional or Bosley at 1(800)BOSLEY1

BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT Regular Strength For Men 2-60ml (65121-102-05)



# BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT REGULAR STRENGTH FOR MEN

minoxidil liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MINO XIDIL (UNII: 5965120 SH1) (MINO XIDIL - UNII:5965120 SH1)	MINOXIDIL	50 mg in 1 mL

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

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:65121-102-05	2 in 1 CARTON	02/09/2017	
1	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	ANDA076239	08/15/2013	

# Labeler - Pure Source, LLC (080354456)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source, LLC		080354456	manufacture(65121-102)	

Revised: 2/2017 Pure Source, LLC