

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

Pure Source, LLC

**BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT Regular Strength
For Men**

**BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT Regular Strength
For Men**

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

- you 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 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 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**(*Minoxidil Topical Solution 5%)
EXTRA STRENGTH FOR MEN**Drug Facts****Active Ingredient** Purpose
Minoxidil 5.0% w/v Hair regrowth treatment for men**Use** to regrow hair on the top of the scalp (vertex only, see picture on side of carton)**Warnings****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, irritated, infected, itchy, 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. 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.**Drug Facts** (continued)**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 regrowth 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 18-39 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% provided more hair regrowth than Minoxidil Topical Solution 2%
- store at controlled room temperature 20° to 25°C (68° to 77° F)

Inactive Ingredients alcohol 20% v/v, propylene glycol 50% v/v, purified water**Questions or comments?**

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

For information call:

(800)BOSLEY1 www.bosleypro.com

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Manufactured for Scientific Hair Research, LLC

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Made in U.S.A.

BOSLEY**PROFESSIONAL STRENGTH**

(*Minoxidil Topical Solution 5%)

HAIR REGROWTH TREATMENT**EXTRA STRENGTH FOR MEN**

(Read enclosed leaflet before use)

This package contains:

- Two 60ML (2 FL.OZ) bottles of Bosley Professional Strength Extra Strength for Men Hair Regrowth Treatment (Two Months Supply)
- One child-resistant dropper applicator

This package also contains an educational leaflet



NDC 65121-102-05

BOSLEY**PROFESSIONAL STRENGTH**

(*Minoxidil Topical Solution 5%)

HAIR REGROWTH TREATMENT

Extra Strength For Men

Clinically Proven to Help Regrow Hair Revitalizes Hair FolliclesTwo Months Supply
2 – 60 ML, (2 FL.OZ.) Bottles**Not For Use By Women**

Bosley Professional Strength Extra Strength for Men Hair Regrowth Treatment (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. Bosley Professional Strength Extra Strength for Men Minoxidil Topical Solution 5% has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, Bosley Professional Strength Extra Strength for Men may not work.

**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)	MINO XIDIL	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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