BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT REGULAR STRENGTH FOR WOMEN- minoxidil liquid Pure Source, LLC

BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT Regular Strength For Women

BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT Regular Strength For Women

Active Ingredient

Minoxidil 2.0% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the scalp

Warnings

For external use only Flammable: keep away from fire or flame

Do not use if

- your degree of hair loss is different than that shown on the side of this carton, because this product may not work for you.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you hair loss is associated with childbirth
- 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. you may need to use this product 2 times a day 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 everyone.

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 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 leaflet
- keep the carton, it contains important information
- in clinical studies with mostly white women aged 18-15 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using woman's minoxidil topical solution 2% for 8 months: 19% had moderate regrowth: 40% had minimal regrowth. This compares with 7% of women reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth, 33% had minimal regrowth).
- 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 Women 2-60ml (65121-101-02)



BOSLEY PROFESSIONAL STRENGTH HAIR REGROWTH TREATMENT REGULAR STRENGTH FOR WOMEN

minoxidil liquid

Product Information									
Product Type			HUMAN OTC DRUG	Item Code	(Source)	NDC	:65121-101		
R	oute of Administr	ation	TOPICAL						
Active Ingredient/Active Moiety									
Ingredient Name Basis of St						th	Strength		
Μ	INO XIDIL (UNII: 59	65120SH1) (MINC	XIDIL - UNII:5965120SH1)		MINOXIDIL		20 mg in 1 mL		
_									
Inactive Ingredients									
			Strength						
A	LCOHOL (UNII: 3K	9958V90M)							
Pl	ROPYLENE GLYCO	DL (UNII: 6DC9Q	167V3)						
W	ATER (UNII: 059QF								
P	ackaging								
#	Item Code]	Package Description	Ma	arketing Start Date	Mar	keting End Date		
1	NDC:65121-101-02	2 in 1 CARTON		02/	09/2017				
1		60 mL in 1 BOTT	TLE; Type 0: Not a Combination P	roduct					
N	Iarketing In	formation							

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(65121-101)

Revised: 2/2017

Pure Source, LLC