

**KERANIQUE FOR WOMEN HAIR REGROWTH TREATMENT- minoxidil liquid**  
**Pure Source, LLC**

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**KERANIQUE For Women Hair Regrowth Treatment**

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**Active ingredient**

Minoxidil 2% w/v

**Purpose**

Hair regrowth treatment

**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
- your 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 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. 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 hand 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 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 of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solutions 2% was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth: 40% had minimal regrowth). This compares with 7% of women reporting moderate 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 USP controlled room temperature 20 ° - 25 °C. (68 ° - 77 °F). Keep tightly closed.

### **Inactive ingredients**

alcohol, propylene glycol, purified water

### **Questions or comments?**

1-888-237-4131

**KERANIQUE For Women Hair Regrowth Treatment 2-60ml (65121-562-02)**

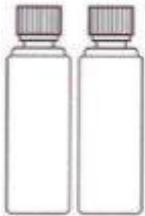
For Women

2% Minoxidil Topical Solution,  
Hair Regrowth Treatment

Keranique for Women  
Minoxidil Topical Solution, 2%  
Hair Regrowth Treatment

NDC# 52512-563-60

**This Package Contains:**



- Two 60 mL (2 X 2 fl oz) Bottles of Minoxidil Topical Solution 2% (two months supply)



- One dropper bottle

- Information leaflet with complete directions on how to use and obtain best results

**KERANIQUE™**  
For Women

MINOXIDIL TOPICAL  
SOLUTION, 2%

**Hair Regrowth Treatment**

Part Number: 40047  
Rev. Date: 3/15/12

**Distributed by:**  
International Hair Institute, LLC  
Jersey City, NJ 07310  
Made in U.S.A.

- Clinically Proven To Help Regrow Hair
- Revitalizes Hair Follicles

TWO MONTHS SUPPLY

2 X 60 mL (2 X 2 fl oz) Bottles

**Keranique for Women**  
**Minoxidil Topical Solution, 2%**  
**Hair Regrowth Treatment**

Minoxidil topical solution 2% is for women who have a general thinning of hair on the top of the scalp as shown. Minoxidil topical solution 2% has been shown to regrow hair in women with the following degrees of thinning hair or hair loss.



If women have more hair loss than shown above, minoxidil topical solution 2% may not work.

Do not use if you have patchy hair loss as shown below.



**Drug Facts**

Active ingredient	Purpose
Minoxidil 2% w/v	Hair regrowth treatment

**Use** to regrow hair on the scalp

**Warnings**

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**Questions or comments?** 1-888-237-4131

**KERANIQUE FOR WOMEN HAIR REGROWTH TREATMENT**

minoxidil liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65121-562
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 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:65121-562-02	1 in 1 CARTON	02/10/2017	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	02/06/2014	

**Labeler** - Pure Source, LLC (080354456)**Establishment**

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-562) , repack(65121-562)

Revised: 2/2017

Pure Source, LLC