

**KERANIQUE 2% HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% solution**  
**Profectus Beauty LLC**

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**Keranique 2% Minoxidil Hair Regrowth Treatment for Women**

Minoxidil 2% w/v

Hair regrowth treatment

**USE**

to regrow hair on scalp

**Flammable: Keep away from fire or flame**

**For external use only**

- Your degree of hair loss is different than that shown on 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 or children.
- Your scalp is red, inflamed, infected, irritated, or painful
- You use other medicines on your 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 eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- Some people have experienced change 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 regrow 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.**

If swallowed, get medical help or contact a Poison Control Center right away.

**DIRECTIONS**

- Apply 1 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
- 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 2% minoxidil topical solutions 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 o - 25 oC. (68 o - 77 oF).

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

1-888-237-4131

Open 24 hours a day, 7 days a week.

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<b>KERANIQUE 2% HAIR REGROWTH TREATMENT FOR WOMEN</b>				
minoxidil 2% solution				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70550-576	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>		
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL		
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>	<b>Strength</b>			
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
<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:70550-576-01	1 in 1 BOX	07/20/2021	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:70550-576-02	2 in 1 BOX	07/20/2021	
2		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:70550-576-04	4 in 1 BOX	07/20/2021	
3		60 mL in 1 BOTTLE, DROPPER; 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	ANDA078176	07/20/2021		

**Labeler -** Profectus Beauty LLC (118310694)