

**KERANIQUE 2% HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil solution  
PROFECTUS BEAUTY, LLC**

-----  
**KERANIQUE Rejuvenate Healthy Hair Regrowth 2% For Women Dropper**

***Drug Facts***

***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 amount 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 year 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 eye 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 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 breastfeeding****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 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 booklet
- keep the carton. It contains important information.
- In clinical studies of mostly white women aged 18-45 years with mild to moderate diagnosis of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women imported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (19% had moderate regrowth, 40% had minimal regrowth). This compares with 7% of women reporting incidental 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 to 25 C (68° to 77° F)**

***Inactive Ingredients***

Alcohol, Propylene Glycol, Purified Water

***Questions or Comments?***

Call toll free 1-888-237-4131 Visit website: [www.keranique.com](http://www.keranique.com)

**Package Labeling:**

**WOMEN'S  
KERANIQUE**

2% Minoxidil Topical  
Solution, USP  
Hair Regrowth Treatment



NDC # 70550-576-01

**KERANIQUE**  
REJUVENATE HEALTHY HAIR REGROWTH

**WOMEN'S  
2% Minoxidil  
Topical Solution,  
USP**

**Hair Regrowth  
Treatment**

Reactivates hair follicles to  
stimulate regrowth

Clinically proven to help regrow hair

Topical Solution

Unscented

One Month Supply  
One 60mL (2 FL.OZ.) Bottle



**WOMEN'S  
KERANIQUE**  
2% Minoxidil Topical  
Solution, USP

Hair Regrowth Treatment  
2% Minoxidil Topical solution is for  
women who have a general thinning  
of hair on the top of the scalp as  
shown. 2% Minoxidil Topical  
Solution 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, 2% Minoxidil Topical  
Solution may not work



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

For best results:  
Apply directly to scalp.  
Use twice daily.

(Read enclosed leaflet before use)

Made in U.S.A.  
Distributed by:  
Profectus Beauty, LLC,  
111 Town Square Pl, Suite 1130  
Jersey City, NJ 07310

**Drug Facts**

**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 amount 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 year 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 eye 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 all women.

**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 breastfeeding.**

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 degree of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution 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 to 25 C (68° to 77° F)

**Inactive Ingredients**

Alcohol, Propylene Glycol, Purified Water

**Questions or Comments?**

Call toll free 1-868-237-4131  
Visit website:  
www.keranique.com



**This Package Contains:**

One 60mL (2 fl oz) Bottle of Women's Keranique (one month supply) With child-resistant dropper applicator Information leaflet with complete directions on how to use and obtain best results.

(Read enclosed leaflet before use)

20053



**KERANIQUE 2% HAIR REGROWTH TREATMENT FOR WOMEN**

minoxidil solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70550-576
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70550-576-01	1 in 1 BOX	07/17/2024	
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	07/17/2024	

**Labeler** - PROPECTUS BEAUTY, LLC (118310694)

Revised: 8/2024

PROPECTUS BEAUTY, LLC