

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

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**Keranique 2% Minoxidil Topical Solution Hair Regrowth Treatment**

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**

- Prime the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist.
- Apply mL with sprayer (6 sprays) 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 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 controlled room temperature 20 ° - 25 °C. (68 ° - 77 °F).

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

1-888-237-4131

Open 24 hours a day, 7 days a week.

# KERANIQUE

THE WOMEN'S HAIR GROWTH EXPERTS®



2% MINOXIDIL TOPICAL SOLUTION USP  
HAIR REGROWTH TREATMENT  
For best results, apply directly to scalp, use twice daily

Keranique for women  
2% Minoxidil Topical Solution USP  
Hair Regrowth Treatment

NDC 70550-578-04

# KERANIQUE

THE WOMEN'S HAIR GROWTH EXPERTS®



2% MINOXIDIL TOPICAL SOLUTION USP  
HAIR REGROWTH TREATMENT

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

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



## HAIR REGROWTH TREATMENT FOR WOMEN

- Reactivates Hair Follicles To Stimulate Regrowth
- Clinically Proven To Help Regrow Hair
- Topical Solution
- Unscented

FOUR MONTH SUPPLY  
FOUR 60 mL (2 FL. OZ.) Bottles

### Drug Facts (continued)

#### Other 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 solution USP was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution USP 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 controlled room temperature 20-25°C (68-77°F).

#### Inactive Ingredients

Alcohol, Propylene Glycol, Purified Water

Questions or comments? 1-888-237-4131

Open 24 hours a day, 7 days a week.

Keranique for women 2% Minoxidil Topical Solution USP Hair Regrowth Treatment

#### This Package Contains:



- Four 60 mL (4 x 2 FL. OZ.) Bottles of 2% Minoxidil Topical Solution USP Hair Regrowth Treatment (four month supply) with child-resistant sprayer pump applicator.
- Information leaflet with complete directions on how to use and obtain best results.

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

Visit website: [www.keranique.com](http://www.keranique.com)

Part number: 40135  
Rev. Date: 05/31/2017

40135



### Drug Facts

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

Use to regrow hair on the scalp.

#### Warnings

##### For external use only

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##### Do not use if

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- 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.
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- 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 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

- Prime the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist.
- Apply 1 mL with sprayer (6 sprays) 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

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## KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN

minoxidil 2% spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70550-578
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)		MINOXIDIL	2 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70550-578-04	4 in 1 BOX	02/25/2022	
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	ANDA078176	02/25/2022		

**Labeler** - PROFECTUS BEAUTY LLC (118310694)

Revised: 2/2022

PROFECTUS BEAUTY LLC