

**KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% spray
INTERNATIONAL HAIR INSTITUTE**

Keranique Hair Regrowth Treatment for Women 2% Minoxidil Topical Solution

Minoxidil 2% w/v

Use to regrow hair on the scalp

Hair regrowth treatment

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree of hair loss is different than 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 or 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. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product 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 heart beat, faintness, or dizziness occurs
- Sudden, unexplained weight gain occurs
- Your hands or feet swell
- Scalp irritation or redness occurs
- You get unwanted facial hair growth
- 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 1mL 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 the 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 moderate degrees of hair loss, the following responses 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 hair regrowth). This compares with the 7% of women reporting moderate hair regrowth after using a placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- Store at controlled room temperature 20 o to 25 oC (68 o to 77 oF)

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

1-888-237-4131

Open 24 hours a day, 7 days a week.

Visit website: www.keranique.com

Drug Facts

Active Ingredient Minoxidil 2% w/v **Purpose** Hair regrowth treatment

Use to regrow hair on the scalp

Warnings

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Stop use and ask a doctor if

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Drug Facts (continued)

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Inactive ingredients alcohol, propylene glycol, purified water

Questions or comments?
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Visit website: www.keranique.com

Keranique Hair Regrowth Treatment for Women (2% Minoxidil Topical Solution)

This Package Contains:

- One (1) 60 mL (2 FL OZ) Bottle of 2% Minoxidil Topical Solution Hair Regrowth Treatment (one month supply) with child-resistant 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

KERANIQUE
THE WOMENS HAIR GROWTH EXPERTS®

FDA APPROVED
TREATMENT FOR WOMEN
(2% MINOXIDIL TOPICAL SOLUTION USP)
For best results, apply directly to scalp. Use twice daily.

NDC 70550-578-01

KERANIQUE
THE WOMENS HAIR GROWTH EXPERTS®

FDA APPROVED
TREATMENT FOR WOMEN
(2% MINOXIDIL TOPICAL SOLUTION USP)

HAIR REGROWTH TREATMENT FOR WOMEN
2% MINOXIDIL TOPICAL SOLUTION USP

PRECISION SPRAYER

- Reactivates Hair Follicles to Stimulate Regrowth
- Clinically Proven to Help Regrow Hair
- Exclusive, Patented Precision Sprayer

ONE MONTH SUPPLY
ONE 60 mL (2 FL OZ) BOTTLE

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

size : 3 x 1+5/8 x 5

ref # : IP160304C2

PROOF 40132-4000-01			DIELINES DO NOT PRINT			
Revision:	Date:	Time:	Revision:	Date:	Time:	SPOT COLORS on this proof are for content/design and not for color
1	11.27.18	10:00am	4	1.8.19	8:00am	
2	11.28.18	7:30am				
3	1.7.19	2:00pm				
3	New file supplied with revised Drug Facts					<input type="checkbox"/> Color OK <input type="checkbox"/> Copy OK <input type="checkbox"/> Approved <input type="checkbox"/> Approved with changes Comments: _____ It is the sole responsibility of the client and/or client's representative to check this proof and certify (as indicated by their signature on this proof) that this proof is approved for final printing. If client and/or client's representative does not sign this proof but approves verbally, it is still assumed that client and/or client's representative has carefully proofread all copy and takes full responsibility for information contained on this proof, including, but not limited to typographical errors or omissions. Signature _____ Date _____
4	Remove "Other Information" on the second panel					



KERANIQUE

THE WOMEN'S HAIR GROWTH EXPERTS™

FDA APPROVED
TOPICAL SOLUTION FOR HAIR GROWTH

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN (2% MINOXIDIL TOPICAL SOLUTION USP)
For best results, apply correctly to scalp. One bottle daily.

NDC 70550-578-03

KERANIQUE

THE WOMEN'S HAIR GROWTH EXPERTS™

FDA APPROVED
TOPICAL SOLUTION FOR HAIR GROWTH

HAIR REGROWTH TREATMENT FOR WOMEN

2% MINOXIDIL TOPICAL SOLUTION USP



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THREE MONTH SUPPLY
THREE 60 mL (2 FL. OZ.) BOTTLES

Drug Facts

Active ingredient Minoxidil 2% w/v

Purpose Hair regrowth treatment

Use to regrow hair on the scalp

Warnings
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alcohol, propylene glycol, purified water

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Open 24 hours a day, 7 days a week.
Visit website: www.keranique.com

This Package Contains:
Keranique Hair Regrowth Treatment for Women (2% Minoxidil Topical Solution)

- Three 60 mL (2 fl. oz.) bottles of 2% Minoxidil Topical Solution Hair Regrowth Treatment with this precision sprayer
- Information leaflet with complete directions on how to see and obtain best results.

Distributed by:
Hormones and Health, LLC
Jersey City, NJ 07310

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN (2% MINOXIDIL TOPICAL SOLUTION USP) is for women who have a general thinning on the top of the scalp (vertex) only as shown below.




2% Minoxidil Topical Solution has been shown to regrow hair in women with the following degrees of thinning hair or hair loss.

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



size : 4+1/4 x 1+5/8 x 5

ref # : IP160304B2

PROOF 40134-4000-01				DIELINES DO NOT PRINT SPOT COLORS on this proof are for content/design and not for color	
Revision:	Date:	Time:	Revision:	Date:	Time:
1	11.27.18	10:00am			
2	1.7.19	200pm			
3	1.8.19	8:00am			
2	New file supplied with revised Drug Facts, etc				
3	Remove "Other Information" on the second panel				
			<input type="checkbox"/> Color OK <input type="checkbox"/> Copy OK <input type="checkbox"/> Approved <input type="checkbox"/> Approved with changes		
Comments: _____					
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Signature _____			Date _____		



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1	1.7.19	2:00pm			
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Signature _____			Date _____		

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN

minoxidil 2% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70550-578
Route of Administration	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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70550-578-01	1 in 1 BOX	07/10/2019	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:70550-578-02	2 in 1 BOX	07/10/2019	
2		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
3	NDC:70550-578-03	3 in 1 BOX	07/10/2019	
3		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	07/10/2019	

Labeler - INTERNATIONAL HAIR INSTITUTE (800337946)

Revised: 8/2019

INTERNATIONAL HAIR INSTITUTE