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.

Flamable: Keep away from fire of 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 dissiness occurs
- Sudden, unexplained weight gain occurs
- Your hands of 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 clincial 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

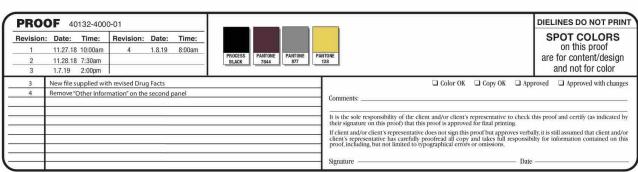
Questions or comments?

1-888-237-4131

Open 24 hours a day, 7 days a week.

Visit website: www.keranique.com







PROOF 40134-4000-01 DIELINES DO NOT PRINT SPOT COLORS Revision: Date: Time: Revision: Date: Time: on this proof 11.27.18 10:00am are for content/design 1.7.19 200pm and not for color 1.8.19 8:00am New file supplied with revised Drug Facts, etc □ Color OK □ Copy OK □ Approved □ Approved with changes Remove "Other Information" on the second panel 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 proferred all copy and takes full responsibility for information contained on this proof, including but not inlinted to typegraphical copy and to the control or typegraphical copy and the control of the con Date -Signature -



PROOF 40133-4000-01	DIELINES DO NOT PRIN
Revision: Date: Time: Revision: Date: Time: 1 1.7.19 2:00pm PANTONE PANTONE 2 1.8.19 8:00am PANTONE BLACK	PANTONE PANTONE PANTONE PANTONE are for content/design and not for color
2 Remove "Other Information" on the second panel	☐ Color OK ☐ Copy OK ☐ Approved ☐ Approved with change
	It is the sole responsibility of the client and/or client's representative to check this proof and certify (as indicated 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 proofered all copy and takes full responsibility for information contained on the proof, including, but not limited to typographical errors or omissions.
	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	
MINO XIDIL (UNII: 5965120 SH1) (MINO XIDIL - UNII:5965120 SH1)	MINOXIDIL	2 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			

P	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