

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% solution
Pure Source, LLC

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% spray

Minoxidil 2% w/v

USE

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

- apply 1mL 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 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 ° to 25 °C (68 ° to 77 °F)

Alcohol, Propylene Glycol, Purified Water



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 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

Part number: 40135
Rev. Date: 09/13/2016

NDC# 70550-578-04

KERANIQUE®

THE WOMEN'S HAIR GROWTH EXPERTS®



**2% MINOXIDIL TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT**

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**

**Keranique for women
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



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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- 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 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 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.

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Directions

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Other Information

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40135



KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN

minoxidil 2% solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65121-578 |
| 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: 059QF0KO0R) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:65121-578-04 | 4 in 1 BOX | 09/13/2022 | |
| 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 | 09/13/2022 | |

Labeler - Pure Source, LLC (080354456)

Revised: 9/2022

Pure Source, LLC