

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

Reference Label Set Id: d8dcf6f7-5b80-4b2c-e053-2995a90a87f2

KERANIQUE Rejuvenate Healthy Hair Regrowth 2% For Women

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 degree 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

- 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 often will not improve results
- continued use is necessary 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 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

Package Labelling:70550-578-01



THE ONLY FDA APPROVED TOPICAL SOLUTION FOR WOMEN'S HAIR REGROWTH

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 degree of hair loss is different than that shown on the side of this carton, because this product may not work for you
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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
- 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

- 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 often will not improve results
- continued use is necessary or hair loss will begin again

Before use, read all information on carton and enclosed booklet ▶

Other Information

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- Store at 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

This Package Contains:

- One 60ml (2 fl oz) Bottle of 2% Minoxidil Topical Solution Hair Regrowth Treatment (one month supply) with child-resistant sprayer pump applicator.
- Information leaflet with complete directions on how to use and obtain best results.

NDC # 70550-578-01

KERANIQUE

REJUVENATE
Healthy Hair Growth

2% Minoxidil Topical Solution USP

Hair Regrowth Treatment for Women

- Reactivates and strengthens hair follicles to stimulate regrowth
- Clinically proven to help regrow hair



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

PATENTED PRECISION SPRAYER

THE ONLY FDA APPROVED TOPICAL SOLUTION FOR WOMEN'S HAIR REGROWTH

KERANIQUE HAIR REGROWTH TREATMENT FOR WOMEN (2% Minoxidil Topical Solution USP)

This solution is for women who have a general thinning on the top of the scalp (vertex only as shown below).

For best results, apply directly to scalp. Use twice daily.

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, Keranique Hair Regrowth Treatment may not work.

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

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Distributed by: Profectus Beauty, LLC, Jersey City, NJ 07310
Questions? Call toll free 1-888-237-4131 or visit www.keranique.com

Package Labelling:70550-578-02

**WOMEN'S
KERANIQUE**

2% Minoxidil Topical
Solution, USP
Hair Regrowth Treatment



NDC # 70550-578-02

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



Two Month Supply
Two 60mL (2 FL.OZ.) Bottles



**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

■ 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 spray (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 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 1-888-237-4131
Visit website:
www.keranique.com

This Package Contains:

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



20050



Package Labelling: 70550-578-03

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



NDC # 70550-578-03

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



Three Month Supply
Three 60mL (2 FL.OZ.) Bottles



**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.....Hair regrowth treatment

Purpose

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.

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Inactive Ingredients
Alcohol, Propylene Glycol, Purified Water

Questions or Comments?

Call toll free 1-866-237-4131
Visit website:
www.keranique.com



This Package Contains:

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

20051



Package Labelling: 70550-578-04

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70550-578-01	1 in 1 BOX	07/17/2024	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:70550-578-02	2 in 1 BOX	07/17/2024	
2		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
3	NDC:70550-578-03	3 in 1 BOX	07/17/2024	
3		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
4	NDC:70550-578-04	4 in 1 BOX	07/17/2024	
4		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	07/17/2024	

Labeler - PROPECTUS BEAUTY, LLC (118310694)

Revised: 8/2024

PROPECTUS BEAUTY, LLC