

**SANTO REMEDIO WOMENS HAIR REGROWTH TREATMENT MINOXIDIL  
UNSCENTED- minoxidil solution  
SANTO REMEDIO LLC**

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**Santo Remedio Women's Hair Regrowth Treatment 2% Minoxidil Topical  
Solution, Unscented**

**Drug Facts**

**Active ingredient**

Minoxidil 2% w/v

**Purpose**

Hair regrowth treatment

**Use**

to regrow hair on the scalp

**Warnings**

**For external use only. For use by men 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 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 all men.

### **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**

- **apply one mL 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 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 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 controlled room temperature 20° to 25°C (68° to 77°F).**

### **Inactive ingredients**

Alcohol, Propylene Glycol, Purified Water

### **Questions or comments?**

### **855-REMEDIO**

Visit Website at [misantoremedio.com](http://misantoremedio.com)

# Package Labeling:



## SPECIFICATIONS

PLEASE APPLY A SPOT UV THE FOLLOWING ELEMENTS

LOGO

**Santo Remedio**

"HAIR REGROWTH TREATMENT"  
\*\*FRONT PANEL ONLY\*\*

**Hair Regrowth Treatment**

PLEASE MAKE SURE TO USE  
**MATTE SOFT TOUCH PAPER FINISH FOR FINISH. SCUFF PROOF.**

### Drug Facts

Active ingredient	Purpose
Minoxidil 2% w/v	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 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 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 breast-feeding.

Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.

Directions - apply one mL 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 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 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, 23% 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? 855-REMEDIO

Visit Website at [misantoremedio.com](http://misantoremedio.com)

WOMEN'S  
**Hair Regrowth Treatment**

2% Minoxidil Topical Solution, USP

This Package Contains:



One 60 mL (2 fl oz) Bottle of Women's Hair Regrowth Treatment (one-month supply).

One child-resistant dropper applicator

Information leaflet with complete directions on how to use and obtain best results

(Read enclosed leaflet before use)

MADE IN USA  
Distributed By:  
Santo Remedio LLC  
Miami, FL 33166  
855-REMEDIO  
[misantoremedio.com](http://misantoremedio.com)

Santo Remedio

WOMEN'S

**Hair Regrowth Treatment**

2% Minoxidil Topical Solution, USP

Santo Remedio

WOMEN'S

**Hair Regrowth Treatment**

2% Minoxidil Topical Solution, USP

Reactivates Hair Follicles To Stimulate Regrowth

CLINICALLY PROVEN TO HELP REGROW HAIR



Topical Solution | Unscented

One Month Supply  
One 60mL (2 fl oz) Bottle

WOMEN'S  
**Hair Regrowth Treatment**

2% Minoxidil Topical Solution, USP

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

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



For Best Results:  
Apply Directly to Scalp.  
Use Twice Daily

LOT NO

EXPIRATION DATE

PS REV 1



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 one mL 2 times a day directly onto the scalp in the hair loss area
- see carton and enclosed leaflet for complete directions
- using more or more often will not improve results
- continued use is necessary, or hair loss will begin again

**Other Information**

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

**Inactive Ingredients** alcohol, propylene glycol, purified water

**Questions?** Call toll-free phone number 855-REMEDIO or reach us online at [misantoremedios.com](http://misantoremedios.com)

**For Best Results: Apply Directly to Scalp Twice Daily**

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PS REV 1

**Santo Remedio**

WOMEN'S  
**Hair Regrowth Treatment**

2% Minoxidil Topical Solution, USP

Reactivates Hair Follicles  
To Stimulate Regrowth

CLINICALLY PROVEN TO  
HELP REGROW HAIR



Topical Solution | Unscented

One Month Supply  
60 mL (2 fl. oz.)

Read and keep carton and leaflet for full product information

**Active Ingredient** Minoxidil 2% w/v

**Warnings**

For external use only.

**Flammable:** Keep away from fire or flame

**Do not use if**

- 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

**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



**Santo Remedio**  
**Women's**  
**Hair Regrowth Treatment**  
**2% Minoxidil**  
**Topical Solution USP Hair Regrowth Treatment**  
**UNSCENTED**

Save this leaflet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Hair Regrowth Treatment contains the only ingredient that is medically proven effective to help regrow hair in women.

Please read this leaflet carefully. It will help you understand how to use Women's Hair Regrowth Treatment and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Women's Hair Regrowth Treatment, you should ask your health care professional or call toll free 855-REMEDIO collect. You can also visit our website at misantoremidio.com

**What is Women's Hair Regrowth Treatment?**

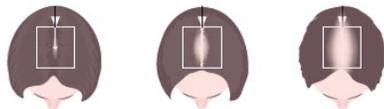
Women's Hair Regrowth Treatment is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

**Who may use Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Hair Regrowth Treatment is for general thinning of hair on the top of the scalp as shown in the illustration below. Women's Hair Regrowth Treatment has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Women's Hair Regrowth Treatment may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.



**Who should NOT use Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp.

Also, Women's Hair Regrowth Treatment will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp. Do not use Women's Hair Regrowth Treatment if hair loss is patchy as shown below.

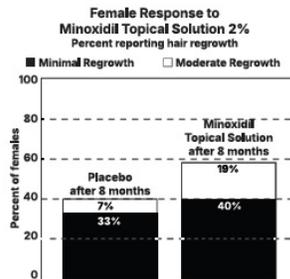


You should ask your doctor if you are unsure of the cause of your hair loss

**Will Women's Hair Regrowth Treatment work for me?**

The amount of hair regrowth is different for each person. Not everyone will respond to Women's Hair Regrowth Treatment. The response to Women's Hair Regrowth Treatment cannot be predicted. No one will be able to grow back all their hair.

In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Minoxidil Topical Solution 2% 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).

**What Minimal, Moderate and Dense Hair Regrowth Mean for You**

	Number of Hairs	Hair Density
<b>Minimal</b>	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of head.
<b>Moderate</b>	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not close together as hairs on the rest of head.
<b>Dense</b>	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of head.

Can Women's Hair Regrowth Treatment be used to prevent hair loss? We do not know if Women's Hair Regrowth Treatment will prevent hair loss.

**How soon can I expect results from using Women's Hair Regrowth Treatment?**

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Women's Hair Regrowth Treatment also takes time. Generally new hair growth is slow for Women's Hair Regrowth Treatment user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth. If you do not see hair regrowth in 4 months, stop using Women's Hair Regrowth Treatment and see your doctor.

When you first begin to use Women's Hair Regrowth Treatment, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

**If Women's Hair Regrowth Treatment is working, what will the hair look like?**

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

**How long do I need to use Women's Hair Regrowth Treatment?**

If you respond to Women's Hair Regrowth Treatment, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from Women's Hair Regrowth Treatment.

**What happens if I completely stop using Women's Hair Regrowth Treatment? Will I keep the new hair?**

Continuous use of Women's Hair Regrowth Treatment is needed to maintain hair regrowth. If you stop using Women's Hair Regrowth Treatment, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

**What is the dosage of Women's Hair Regrowth Treatment?**

You should apply a dose (1 mL) of Women's Hair Regrowth Treatment directly onto scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please, refer to the "Directions for Use" section of the leaflet.

**What if I miss a dose or forget to use Women's Hair Regrowth Treatment?**

If you miss one or two daily doses of Women's Hair Regrowth Treatment, just continue with your next dose. You should not make up for missed doses.

**Can I use Women's Hair Regrowth Treatment more than two times a day? Will it work faster, better?**

No. Hair Regrowth Treatment will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of Minoxidil Topical Solution 2% needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

**What are the most common side effects with Women's Hair Regrowth Treatment?**

The most common side effects are itching and other skin irritations of the treated area of the scalp. Women's Hair Regrowth Treatment contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Women's Hair Regrowth Treatment accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

**What kind of shampoo should I use with Women's Hair Regrowth Treatment?**

If you wash your scalp before applying Women's Hair Regrowth Treatment, use a mild shampoo.

**Can I use hair sprays, mousses, conditioners, gels, etc.?**

Yes. There is no reason to change your usual hair care routine when using Women's Hair Regrowth Treatment. However, you should apply Women's Hair Regrowth Treatment first and wait for it to dry before applying your styling aids.

**Can I have my hair colored or permed or use hair relaxers while using Women's Hair Regrowth Treatment?**

Yes. We have no information that these treatments change the effect of Women's Hair Regrowth Treatment. However, to avoid possible scalp irritation, you should make sure all of the Women's Hair Regrowth Treatment has been washed off the hair and scalp before using these chemicals.

**Can I apply Women's Hair Regrowth Treatment and wash my hair an hour later?**

No. For Women's Hair Regrowth Treatment to work best, you should allow Women's Hair Regrowth Treatment to remain on the scalp for about 4 hours before washing.

**Can I go swimming or out in the rain?**

Yes. Avoid washing off the Women's Hair Regrowth Treatment. If possible, apply Women's Hair Regrowth Treatment to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Women's Hair Regrowth Treatment.

**Can Women's Hair Regrowth Treatment produce unwanted hair?**

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Women's Hair Regrowth Treatment to areas other

than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Women's Hair Regrowth Treatment.

If you experience unwanted hair, discontinue using Women's Hair Regrowth Treatment and see your doctor for recommendations about appropriate treatment. After stopping use of Women's Hair Regrowth Treatment, the unwanted hair, if caused by the use of Hair Regrowth Treatment, should go away over time.

You can take steps to decrease the chances for unwanted hair growth:

1. limit the application of Hair Regrowth Treatment only to the scalp,
2. if you use your hands to apply Hair Regrowth Treatment, wash your hands thoroughly afterwards, and
3. allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Women's Hair Regrowth Treatment

**Can I use Women's Hair Regrowth Treatment for baldness or hair loss in babies and children?**

No. Women's Hair Regrowth Treatment must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of Women's Hair Regrowth Treatment?**

**For external use only**

**Flammable: Keep away from fire or flame**

**Do not use if**

- your degree of hair loss is more than that shown in the illustration on page 1 of this leaflet, 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 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. Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**What factors may increase the risk of serious side effects with Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment should be applied only to the scalp. The risk of side effects may be greater when Women's Hair Regrowth Treatment is applied to other parts of the body.

**Directions for Use**

1. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
2. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and **apply one mL 2 times a day** directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Women's Hair Regrowth Treatment.

**Using the Dropper Applicator**



1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

If you have any other questions, ask your health care professional or call toll free 855-REMEDIO collect. You can also visit our website at [misantoremedio.com](http://misantoremedio.com)

**Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).**

Save this leaflet for future reference.

Santo Remedio LLC  
Miami, FL 33166  
U.S.A.

PS  
REV 1

## Package Labeling:



## SPECIFICATIONS

PLEASE APPLY A SPOT UV  
THE FOLLOWING ELEMENTS

LOGO

**Santo Remedio**

"HAIR REGROWTH TREATMENT"  
\*\*FRONT PANEL ONLY\*\*

**Hair Regrowth  
Treatment**

PLEASE MAKE SURE TO USE  
MATTE SOFT TOUCH  
PAPER FINISH FOR FINISH.  
SCUFF PROOF.

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Minoxidil 2% w/v	Hair regrowth treatment
<b>Use to:</b> regrow hair on the scalp	
<b>Warnings</b> For external use only.	
<b>Flammable:</b> Keep away from fire or flame	
<b>Do not use if:</b> • 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 children • 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	
<b>Ask a doctor before use if you have heart disease</b>	
<b>When using this product:</b> • 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 amount of hair regrowth is different for each person. This product will not work for all women.	
<b>Stop use and ask a doctor if:</b> • 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	
<b>May be harmful if used when pregnant or breast-feeding.</b> Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions:</b> • apply one mL, 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	
<b>Other information:</b> • 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 healthy white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 90% of women, or 8 months (50% had moderate regrowth, 40% had minimal regrowth). This compares with 2% of women receiving placebo hair regrowth after using the placebo, the liquid without minoxidil. In 8 months (17% had moderate regrowth, 24% had minimal regrowth).	
<b>Store at controlled room temperature 20° to 25°C (68° to 77°F).</b>	
<b>Inactive ingredients:</b> alcohol, Propylene Glycol, Purified Water	
<b>Questions or comments?</b> 855-REMEDIO • Visit Website at <a href="http://misantoremedio.com">misantoremedio.com</a>	

LOT NO.  
EXPIRATION DATE

PS REV 1



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 one mL 2 times a day directly onto the scalp in the hair loss area
- see carton and enclosed leaflet for complete directions
- using more or more often will not improve results
- continued use is necessary, or hair loss will begin again

### Other Information

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

**Inactive Ingredients** alcohol, propylene glycol, purified water

**Questions?** Call toll-free phone number 855-REMEDIO or reach us online at [misantoremedio.com](http://misantoremedio.com)

**For Best Results: Apply Directly to Scalp Twice Daily**

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WOMEN'S  
**Hair Regrowth  
Treatment**

2% Minoxidil Topical Solution, USP

Reactivates Hair Follicles  
To Stimulate Regrowth

CLINICALLY PROVEN TO  
HELP REGROW HAIR



Topical Solution | Unscented

One Month Supply  
60 mL (2 fl. oz.)

Read and keep carton and leaflet for full product information

**Active Ingredient** Minoxidil 2% w/v

### Warnings

For external use only.

**Flammable:** Keep away from fire or flame

### Do not use if

- 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

### 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



**What if I miss a dose or forget to use Women's Hair Regrowth Treatment?**

If you miss one or two daily doses of Women's Hair Regrowth Treatment, just continue with your next dose. You should not make up for missed doses.

**Can I use Women's Hair Regrowth Treatment more than two times a day? Will it work faster, better?**

No. Hair Regrowth Treatment will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of Minoxidil Topical Solution 2% needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

**What are the most common side effects with Women's Hair Regrowth Treatment?**

The most common side effects are itching and other skin irritations of the treated area of the scalp. Women's Hair Regrowth Treatment contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Women's Hair Regrowth Treatment accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

**What kind of shampoo should I use with Women's Hair Regrowth Treatment?**

If you wash your scalp before applying Women's Hair Regrowth Treatment, use a mild shampoo.

**Can I use hair sprays, mousses, conditioners, gels, etc.?**

Yes. There is no reason to change your usual hair care routine when using Women's Hair Regrowth Treatment. However, you should apply Women's Hair Regrowth Treatment first and wait for it to dry before applying your styling aids.

**Can I have my hair colored or permed or use hair relaxers while using Women's Hair Regrowth Treatment?**

Yes. We have no information that these treatments change the effect of Women's Hair Regrowth Treatment. However, to avoid possible scalp irritation, you should make sure all of the Women's Hair Regrowth Treatment has been washed off the hair and scalp before using these chemicals.

**Can I apply Women's Hair Regrowth Treatment and wash my hair an hour later?**

No. For Women's Hair Regrowth Treatment to work best, you should allow Women's Hair Regrowth Treatment to remain on the scalp for about 4 hours before washing.

**Can I go swimming or out in the rain?**

Yes. Avoid washing off the Women's Hair Regrowth Treatment. If possible, apply Women's Hair Regrowth Treatment to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Women's Hair Regrowth Treatment.

**Can Women's Hair Regrowth Treatment produce unwanted hair?**

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Women's Hair Regrowth Treatment to areas other

than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Women's Hair Regrowth Treatment. If you experience unwanted hair, discontinue using Women's Hair Regrowth Treatment and see your doctor for recommendations about appropriate treatment. After stopping use of Women's Hair Regrowth Treatment, the unwanted hair, if caused by the use of Hair Regrowth Treatment, should go away over time.

You can take steps to decrease the chances for unwanted hair growth:

1. limit the application of Hair Regrowth Treatment only to the scalp,
2. if you use your hands to apply Hair Regrowth Treatment, wash your hands thoroughly afterwards, and
3. allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Women's Hair Regrowth Treatment

**Can I use Women's Hair Regrowth Treatment for baldness or hair loss in babies and children?**

No. Women's Hair Regrowth Treatment must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of Women's Hair Regrowth Treatment?**

**For external use only**  
**Flammable: Keep away from fire or flame**

**Do not use if**

- your degree of hair loss is more than that shown in the illustration on page 1 of this leaflet, 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 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. Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**What factors may increase the risk of serious side effects with Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment should be applied only to the scalp. The risk of side effects may be greater when Women's Hair Regrowth Treatment is applied to other parts of the body.

**Directions for Use**

1. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
2. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and **apply one mL 2 times a day** directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Women's Hair Regrowth Treatment.

**Using the Dropper Applicator**



1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

If you have any other questions, ask your health care professional or call toll free **855-REMEDIO** collect. You can also visit our website at [misantoremidio.com](http://misantoremidio.com)

**Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).**

Save this leaflet for future reference.

Santo Remedio LLC  
Miami, FL 33166  
U.S.A.

PS  
REV 1

**Santo Remedio**  
**Women's**  
**Hair Regrowth Treatment**  
**2% Minoxidil**  
**Topical Solution USP Hair Regrowth Treatment**  
 UNSCENTED

Save this leaflet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Hair Regrowth Treatment contains the only ingredient that is medically proven effective to help regrow hair in women.

Please read this leaflet carefully. It will help you understand how to use Women's Hair Regrowth Treatment and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Women's Hair Regrowth Treatment, you should ask your health care professional or call toll free 855-REMEDIO collect. You can also visit our website at [misantoremedio.com](http://misantoremedio.com)

**What is Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

**Who may use Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Hair Regrowth Treatment is for general thinning of hair on the top of the scalp as shown in the illustration below. Women's Hair Regrowth Treatment has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Women's Hair Regrowth Treatment may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.**



**Who should NOT use Women's Hair Regrowth Treatment?**

Women's Hair Regrowth Treatment will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp.

Also, Women's Hair Regrowth Treatment will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp. Do not use Women's Hair Regrowth Treatment if hair loss is patchy as shown below.

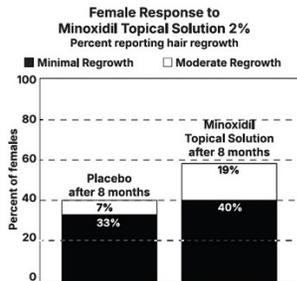


**You should ask your doctor if you are unsure of the cause of your hair loss**

**Will Women's Hair Regrowth Treatment work for me?**

The amount of hair regrowth is different for each person. Not everyone will respond to Women's Hair Regrowth Treatment. The response to Women's Hair Regrowth Treatment cannot be predicted. No one will be able to grow back all their hair.

In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Minoxidil Topical Solution 2% 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).

**What Minimal, Moderate and Dense Hair Regrowth Mean for You**

	Number of Hairs	Hair Density
<b>Minimal</b>	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of head.
<b>Moderate</b>	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not close together as hairs on the rest of head
<b>Dense</b>	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of head.

**Can Women's Hair Regrowth Treatment be used to prevent hair loss?** We do not know if Women's Hair Regrowth Treatment will prevent hair loss.

**How soon can I expect results from using Women's Hair Regrowth Treatment?**

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Women's Hair Regrowth Treatment also takes time. Generally new hair growth is slow for Women's Hair Regrowth Treatment user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth. If you do not see hair regrowth in 4 months, stop using Women's Hair Regrowth Treatment and see your doctor.

When you first begin to use Women's Hair Regrowth Treatment, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

**If Women's Hair Regrowth Treatment is working, what will the hair look like?**

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

**How long do I need to use Women's Hair Regrowth Treatment?**

If you respond to Women's Hair Regrowth Treatment, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from Women's Hair Regrowth Treatment.

**What happens if I completely stop using Women's Hair Regrowth Treatment? Will I keep the new hair?**

Continuous use of Women's Hair Regrowth Treatment is needed to maintain hair regrowth. If you stop using Women's Hair Regrowth Treatment, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

**What is the dosage of Women's Hair Regrowth Treatment?**

You should apply a dose (1 mL) of Women's Hair Regrowth Treatment directly onto scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please, refer to the "Directions for Use" section of the leaflet.

**SANTO REMEDIO WOMENS HAIR REGROWTH TREATMENT**  
**MINOXIDIL UNSCENTED**

minoxidil solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81352-561
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81352-561-00	1 in 1 BOX	11/08/2024	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:81352-561-03	3 in 1 BOX	11/08/2024	
2		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	11/08/2024	

**Labeler** - SANTO REMEDIO LLC (117456185)

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(81352-561)

Revised: 12/2024

SANTO REMEDIO LLC