

**STAFENIT HAIR REGROWTH TREATMENT TOPICAL MINOXIDIL-
minoxidil solution
Cozesmo**

Stafenit Hair Regrowth Treatment Topical Solution 5% Minoxidil

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see picture on side of carton)

Warnings

For external use only. For use by men only.

Flammable: Keep away from fire or flame

Do not use if:

- you are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution is not intended for frontal baldness or receding hairline
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- 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. 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 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.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- **store at controlled room temperature 20° to 25°C (68° to 77°F).**

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

1-703-540-5353

- Visit Website at www.stafenit.com

Package Labeling:

3.125"

Drug Facts	
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When using this product	
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Inactive ingredients Alcohol, Propylene Glycol, Purified Water	
Questions or comments? 1-703-540-5353	
• Visit Website at www.stafenit.com	

STAFENIT®
5% Minoxidil
EXTRA STRENGTH FOR MEN
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

This Package Contains:



5% Minoxidil Topical Solution USP
(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:
Stafenit
5F-7, 203, Gyeongin-ro,
Sosa-gu, Bucheon-si,
Gyeonggi-do, South Korea
Zip Code: 14709



5% Minoxidil
TOPICAL SOLUTION USP

NDC XXXXX-XXX-XX

STAFENIT®
5% Minoxidil
EXTRA STRENGTH FOR MEN
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

Reactivates hair follicles
to stimulate regrowth
Clinically proven to help
regrow hair

Topical Solution
Unscented



Made in U.S.A.

STAFENIT®
60ml (2 fl.oz.)

STAFENIT®
5% Minoxidil
EXTRA STRENGTH FOR MEN
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

5% Minoxidil Topical Solution, USP is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. 5% Minoxidil Topical Solution, USP has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Solution 5% may not work.

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

NDC XXXXX-XXX-XX

5% Minoxidil

EXTRA STRENGTH FOR MEN

TOPICAL SOLUTION USP

HAIR REGROWTH TREATMENT

Reactivates hair follicles to stimulate regrowth
Clinically proven to help regrow hair

Topical Solution
Unscented



STAFENIT®
60ml(2 fl.oz.)

Active Ingredient Minoxidil 5% w/v

Warnings
For external use only. For use by men only.

Flammable: Keep away from fire or flame

Do not use if • you are a woman • you have no family history of hair loss • your hair loss is sudden and/or patchy • 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

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 number 1-703-540-5353 or Visit website at www.stafenit.com

For Best Results: Apply Directly to

Scalp Twice Daily

Made in USA
Distributed by:
Stafenit
5F-7, 203, Gyeongin-ro, Sosa-gu, Bucheon-si, Gyeonggi-do, South Korea
Zip Code: 14709

EXTRA STRENGTH FOR MEN

5% Minoxidil

TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT
Unscented

What is Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

5% MINOXIDIL TOPICAL SOLUTION Extra Strength is a colorless liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

5% MINOXIDIL TOPICAL SOLUTION Extra Strength is for use only by men. 5% MINOXIDIL TOPICAL SOLUTION Extra Strength may be appropriate for you if you are a male at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp (vertex only, as shown on the

hair or hair loss. If you have no family history of gradual thinning hair or of gradual hair loss, or your hair loss is patchy, see your doctor.

Who should NOT use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

Women should not use 5% MINOXIDIL TOPICAL SOLUTION Extra Strength because studies have shown it works no better in women than Women's 2% Minoxidil Topical Solution. Some women may also grow facial hair. In addition, 5% MINOXIDIL TOPICAL SOLUTION Extra Strength may be harmful if used during pregnancy or breast-feeding.

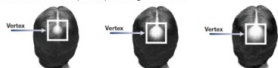
5% MINOXIDIL TOPICAL SOLUTION Extra Strength should not be used on babies or for children under 18 years old.

Save this leaflet for future reference.

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.

Please read this leaflet carefully. It will help you understand how to use 5% MINOXIDIL TOPICAL SOLUTION Extra Strength for Men and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using 5% MINOXIDIL TOPICAL SOLUTION Extra Strength for Men, you should ask your health care professional or contact us at Cozemo at Phone # (703) 540-5353. Monday - Friday, 9:00AM - 3:00PM (EST). You can also contact us at our website at www.cozemo.com

Illustration below. It is not intended for frontal baldness or a receding hairline. The common inherited thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.



5% MINOXIDIL TOPICAL SOLUTION Extra Strength is for men with hair loss or thinning hair that begins on the vertex of the scalp. 5% MINOXIDIL TOPICAL SOLUTION Extra Strength is more likely to regrow hair in men with hair loss in the range shown above. If men have more hair loss than shown, 5% MINOXIDIL TOPICAL SOLUTION Extra Strength may not work. Many of those experiencing hair loss have other family members with gradual thinning

5% MINOXIDIL TOPICAL SOLUTION Extra Strength will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp.

Also, 5% MINOXIDIL TOPICAL SOLUTION Extra Strength 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 if you are not sure of the reason for your hair loss.

Will Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to 5% MINOXIDIL TOPICAL SOLUTION Extra Strength. The response to 5% MINOXIDIL TOPICAL SOLUTION Extra Strength cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

What Minimal, Moderate and Dense Hair Regrowth Will Mean for You?

	Number of Hairs	Hair Density
Minimal	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 the head.
Moderate		
Dense	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of the head.

How soon can I expect results from using Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with 5% MINOXIDIL TOPICAL SOLUTION Extra Strength also takes time. Results may be seen as early as 2 months with twice daily use. For some men, it may take at least 4 months for results to be seen. If you do not see any results after 4 months, stop using 5% MINOXIDIL TOPICAL SOLUTION Extra Strength.

When you first begin to use 5% MINOXIDIL TOPICAL SOLUTION Extra Strength, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hairs in order to regrow more new hairs. This temporary increase in hair loss is expected and is a part of the

If you experience hair regrowth, continued use of 5% MINOXIDIL TOPICAL SOLUTION Extra Strength is necessary, or the hair loss will begin again. In studies with 5% Minoxidil Topical Solution USP, hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

What happens if I completely stop using Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

Continuous use of 5% MINOXIDIL TOPICAL SOLUTION Extra Strength is needed to maintain hair regrowth. If you stop using 5% MINOXIDIL TOPICAL SOLUTION Extra Strength, you will lose your newly regrown hair in 3 to 4 months.

When do I use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

Apply 5% MINOXIDIL TOPICAL SOLUTION Extra Strength once in the morning and once at night. The nighttime application should occur 2 to 4 hours before going to bed to allow for drying. Each bottle should last one month, if used as directed.

What if I miss a

Moderate	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as dense together as hairs on the rest of the head.
Dense	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of the head.

process for how 5% MINOXIDIL TOPICAL SOLUTION Extra Strength regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength is working, what will the hair look like?

At first, hair growth is usually soft, downy, colorless hairs (like peach fuzz). 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 Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

How do I use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

For best results, apply 1 mL 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Each bottle should last one month, if used as directed. Allow time for Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength to dry completely before wearing a hat, or lying on a pillow, etc. Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength may cause staining of clothing or linens if damp on the scalp.

When applying Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength at night, be sure to allow 2 to 4 hours to dry completely. Never take this product by mouth or apply to other parts of the body.

Can I use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength more than twice a day? Will it work faster, better?

No. 5% MINOXIDIL TOPICAL SOLUTION Extra Strength 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 5% Minoxidil Topical Solution USP needed to get the best results. More frequent use or larger doses have not

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If you wash your scalp before applying 5% MINOXIDIL TOPICAL SOLUTION Extra Strength, use a mild shampoo.

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

Yes. Hair sprays, spitz, or styling aids may be used on your hair while using 5% MINOXIDIL TOPICAL SOLUTION Extra Strength. For best results, 5% MINOXIDIL TOPICAL SOLUTION Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying 5% MINOXIDIL TOPICAL SOLUTION Extra Strength first, and then applying styling products and style as usual. Keep in mind that your best results will be seen with proper application.

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Can I have my hair colored or permed or use hair relaxers while using Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers changes the effect of 5% MINOXIDIL TOPICAL SOLUTION Extra Strength. However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we recommend the following precautions:

- To avoid possible scalp irritation, you should make sure all the 5% MINOXIDIL TOPICAL SOLUTION Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
- For best results, do not apply 5% MINOXIDIL TOPICAL SOLUTION Extra Strength on the same day that you use a chemical treatment on your hair.

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Can I go swimming or out in the rain?

Yes. Avoid washing off the 5% MINOXIDIL TOPICAL SOLUTION. If possible, apply 5% MINOXIDIL TOPICAL SOLUTION 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 5% MINOXIDIL TOPICAL SOLUTION.

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Can I apply Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength and wash my hair an hour later?

No. For 5% MINOXIDIL TOPICAL SOLUTION Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.

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Directions for Use

When applying Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength, make sure the medicine comes in direct contact with the scalp.

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Warnings

For external use only. For use by men only
Flammable: Keep away from fire or flame

Do not use if

- you are a woman
- your amount of hair loss is different than that shown in the illustration on page 1 of this leaflet, or your hair loss is on the front of the scalp. 5% minoxidil topical solution is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss

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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.

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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.

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What are the most common side effects with Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength?

The most common side effects are itching and skin irritation of the treated area of the scalp. If scalp irritation continues, stop use and see a doctor. 5% MINOXIDIL TOPICAL SOLUTION Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If 5% MINOXIDIL TOPICAL SOLUTION Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength produce unwanted hair growth?

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair,

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Can I use Men's 5% MINOXIDIL TOPICAL SOLUTION Extra Strength for baldness or hair loss in babies or children?

No. 5% MINOXIDIL TOPICAL SOLUTION Extra Strength must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your health care professional or call 703-540-5353 (collect). You can also visit our website at www.cozemo.com

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F). Save this leaflet for future reference.

Cozemo
Dulchicoms, Gyeonggi-do, 14709, South Korea

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STAFENIT HAIR REGROWTH TREATMENT TOPICAL MINOXIDIL minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85097-576
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85097-576-00	1 in 1 BOX	12/11/2024	
1		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	ANDA076239	12/11/2024	

Labeler - Cozesmo (963390296)

Revised: 1/2025

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