

**ETADERM MENS MINOXIDIL HAIR REGROWTH TREATMENT EXTRA STRENGTH-
minoxidil solution
NUEPHASE LLC**

Etaderm Men's Minoxidil 5% Hair Regrowth Treatment Extra Strength

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on 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, 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:

- 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 one mL 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. • 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 18-45 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?

(424) 354-4370

- Visit Website at www.etaderm.com

Package Labeling:

EXTRA STRENGTH | 5% MINOXIDIL TOPICAL SOLUTION | USP HAIR REGROWTH TREATMENT

Minoxidil 5% w/v Hair regrowth treatment for men

- Visit Website at www.etaderm.com

Add Label part #
Rev.

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

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



Expiration Date

XXXX-XX-XX

Read and keep carton and leaflet for full product information

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

ETADERM

MEN'S MINOXIDIL 5%

EXTRA STRENGTH
5% MINOXIDIL TOPICAL SOLUTION, USP
HAIR REGROWTH TREATMENT

Reactivates Hair Follicles
To Stimulate Regrowth

Clinically Proven
to Help Regrow Hair

Topical Solution

Fragrance Free

Not for Use by Women

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

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 sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area • see enclosed leaflet for complete Directions for Use • using more or more often will not improve result • continued use is necessary, or hair loss will begin again

Inactive Ingredients

Alcohol, Propylene Glycol, Purified Water

Questions? Call (424) 354-4370

Visit Website at www.etaderm.com

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



Lot No.
Expiration
Date

Made in USA
Distributed By:

ETADERM
9750 NW
Miami, FL 33172

Add Label part #
Rev.

Package Labeling:

MEN'S Mens Minoxidil 5% EXTRA STRENGTH

5% Minoxidil Topical Solution, USP

HAIR REGROWTH TREATMENT

Unscented

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.

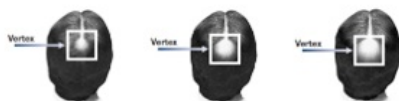
Please read this leaflet carefully. It will help you understand how to use **Mens Minoxidil 5% Extra Strength** for Men and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using **Mens Minoxidil 5% Extra Strength** for Men, you should ask your health care professional or contact us at ETA Derm at Phone# (424) 354-4370. Monday - Friday; 9:00 AM - 5:00 PM (EST). You can also contact us at our website at www.eta-derm.com

What is Men's **Mens Minoxidil 5% Extra Strength**?

Mens Minoxidil 5% 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 **Mens Minoxidil 5% Extra Strength**?

Mens Minoxidil 5% Extra Strength is for use only by men. **Mens Minoxidil 5% 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 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.



Mens Minoxidil 5% Extra Strength is for men with hair loss or thinning hair that begins on the vertex of the scalp. **Mens Minoxidil 5% Extra Strength** is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, **Mens Minoxidil 5% Extra Strength** may not work. Many of those experiencing hair loss have other family members with gradual thinning 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 **Mens Minoxidil 5% 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, **Mens Minoxidil 5% Extra Strength** may be harmful if used during pregnancy or breastfeeding.

Mens Minoxidil 5% Extra Strength should not be used on babies or for children under 18 years old.

Mens Minoxidil 5% 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, **Mens Minoxidil 5% 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 **Mens Minoxidil 5% Extra Strength** work for me?

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

However, to see your best results with **Mens Minoxidil 5% Extra Strength**, make sure you get the medicine directly to the scalp and apply it twice a day, every day. You may get better results if you have been losing your hair for a short period of time or have little hair loss. However, for some men **Mens Minoxidil 5% Extra Strength** may not work.

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	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as close 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.

How soon can I expect results from using Men's **Mens Minoxidil 5% Extra Strength**?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with **Mens Minoxidil 5% 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

Mens Minoxidil 5% Extra Strength. When you first begin to use **Mens Minoxidil 5% 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 process for how **Mens Minoxidil 5% Extra Strength** regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If Men's **Mens Minoxidil 5% 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 **Mens Minoxidil 5% Extra Strength**?

If you experience hair regrowth, continued use of **Mens Minoxidil 5% Extra Strength** is necessary, or the hair loss will begin again. In studies with 5% Minoxidil Topical Solution Extra Strength, 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 **Mens Minoxidil 5% Extra Strength**? Will I keep the new hair?

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

How do I use Men's **Mens Minoxidil 5% Extra Strength**?

For best results, apply 1 mL (6 sprays) 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 **Mens Minoxidil 5% Extra Strength** to dry completely before wearing a hat, or lying on a pillow, etc. Men's **Mens Minoxidil 5% Extra Strength** may cause staining of clothing or linens if damp on the scalp. When applying Your Men's **Mens Minoxidil 5% 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.

When do I use Men's **Mens Minoxidil 5% Extra Strength**?

Apply **Mens Minoxidil 5% 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 dose or forget to use Men's **Mens Minoxidil 5% Extra Strength**? If you miss one or two daily doses of **Mens Minoxidil 5% Extra Strength**, just continue with your next dose. You should not make up for missed doses.

Can I use Men's **Mops** Minoxidil 5% Extra Strength more than twice a day? Will it work faster, better?
No. **Mops** Minoxidil 5% 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 **Mops** Minoxidil 5% Extra Strength 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 kind of shampoo should I use with Men's **Mops Minoxidil 5% Extra Strength?**
If you wash your scalp before applying **Mops** Minoxidil 5% Extra Strength, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.?
Yes. Hair sprays, spritz, or styling aids may be used on your hair while using **Mops** Minoxidil 5% Extra Strength. For best results, **Mops** Minoxidil 5% Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying **Mops** Minoxidil 5% 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.

Can I have my hair colored or permed or use hair relaxers while using Men's **Mops** Minoxidil 5% Extra Strength?
Yes. We have no evidence that coloring or perming your hair or that the use of relaxers changes the effect of **Mops** Minoxidil 5% 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 **Mops** Minoxidil 5% Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
- For best results, do not apply **Mops** Minoxidil 5% Extra Strength on the same day that you use a chemical treatment on your hair.
- Do not use **Mops** Minoxidil 5% Extra Strength for 24 hours after using any chemicals to make sure your scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue use of **Mops** Minoxidil 5% Extra Strength as usual.
- Simply restart your normal Men's **Mops** Minoxidil 5% Extra Strength routine. There is no need to use more Men's **Mops** Minoxidil 5% Extra Strength to make up missed applications. Missing 1 day of Men's **Mops** Minoxidil 5% Product Name Extra Strength will not affect your hair regrowth results.

Can I apply Men's **Mops** Minoxidil 5% Extra Strength and wash my hair an hour later?
No. For **Mops** Minoxidil 5% Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Directions for Use
When applying Men's **Mops** Minoxidil 5% Extra Strength, make sure the medicine comes in direct contact with the scalp. The medicine will not work if it is sprayed only on your hair and does not reach your scalp.

Carefully follow the instructions below to use the child-resistant sprayer pump to apply Men's **Mops** Minoxidil 5% Extra Strength

- Remove the bottle of Men's **Mops** Minoxidil 5% Extra Strength from the carton.
- Firmly hold the bottle upright with the turning wheel on the back of the bottle facing you. Push in the small tab located to the bottom right of the turning wheel.
- While holding the tab in, press down on the top of the sprayer and turn the upper part of the sprayer with the turning wheel to the left until the spray nozzle is centered between the beveled grooves on the front of the bottle.
- Then prime the sprayer by holding the bottle upright and pumping the sprayer 5 times to ensure delivery of a full spray. Be careful not to inhale the mist.
- Aim the sprayer at your area of thinning hair or hair loss and pump the sprayer 6 times to apply a 1 mL dose twice a day.
- After applying Men's **Mops** Minoxidil 5% Extra Strength, use the turning wheel to turn the sprayer cap back to the right to release the tab which places the sprayer nozzle behind the sprayer cap wall. Make sure the sprayer cannot be pushed or pumped before putting the bottle away.



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
- you are under 18 years of age. Do not use on babies and children.
- 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.

What are the most common side effects with Men's **Mops Minoxidil 5% 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. **Mops** Minoxidil 5% Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If **Mops** Minoxidil 5% Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Men's **Mops Minoxidil 5% 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, stop **use** **Mops** Minoxidil 5% **a-Extra** Strength. Over time, the unwanted hair, if caused by **Mops** Minoxidil 5% Extra Strength, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

- limit the application of **Mops** Minoxidil 5% Extra Strength only to the scalp.
- if you use your hands to apply **Mops** Minoxidil 5% Extra Strength, wash your hands well immediately afterwards; and
- after your nighttime application of **Mops** Minoxidil 5% Extra Strength, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use Men's **Mops Minoxidil 5% Extra Strength for baldness or hair loss in babies or children?**
No. **Mops** Minoxidil 5% 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 toll free (424) 354-4370. You can also visit our website at www.etaderm.com

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

Save this leaflet for future reference.

ETA Derm
9750 NW
Miami, FL 33172

Label part#

Label rev. date

ETADERM MENS MINOXIDIL HAIR REGROWTH TREATMENT EXTRA STRENGTH

minoxidil solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84180-878
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84180-878-00	1 in 1 BOX	08/29/2025	
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	08/29/2025	

Labeler - NUEPHASE LLC (118900101)**Registrant** - Pure Source, LLC (080354456)

Revised: 9/2025

NUEPHASE LLC