

**FOLIGAIN PROFESSIONAL SERIES EXTRA STRENGTH FOR MEN MINOXIDIL HAIR  
REGROWTH TREATMENT- minoxidil solution**  
WR Group, Inc.

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**Foligain Professional Series Extra Strength For Men Minoxidil USP 5% Hair  
Regrowth Treatment**

***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 women only. Flammable:**Keep away from fire or flame.

**Do not use if you:**

- are a woman.
- have hair loss other than that shown on the side of this carton, because this product may not work for you.
- have no family history of hair loss.
- have sudden and/or patchy hair loss.
- do not know the reason for your hair loss.
- are under 18 years of age.
- have a red, inflamed, infected, irritated or painful-feeling scalp.
- 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 you experience:**

- chest pain, rapid heartbeat, faintness, or dizziness.
- sudden, unexplained weight gain.
- swelling of the hands or feet.
- scalp irritation or redness.
- unwanted facial hair growth.
- no 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***

- Apply 1 mL with dropper two (2) times a day directly onto the scalp in the hair loss area.
- Using more product, or using product 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?***

- call us at +1 (844) 473-7279
- visit [www.foligain.com](http://www.foligain.com)

# Package Labeling:

FOLIGAIN<sup>®</sup>  
PROFESSIONAL SERIES

EXTRA STRENGTH FOR MEN

# Minoxidil

TOPICAL SOLUTION USP, 5%

THREE MONTH SUPPLY

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#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT

FOLIGAIN<sup>®</sup>  
PROFESSIONAL SERIES

EXTRA STRENGTH FOR MEN

# Minoxidil

TOPICAL SOLUTION USP, 5%

HAIR REGROWTH TREATMENT

Clinically Proven to Help Regrow Hair

Reactivates Hair Follicles to Stimulate Growth

NDC XXXXX-XXX-XX

NOT TO BE USED BY WOMEN

THREE MONTH SUPPLY

UNSCENTED TOPICAL SOLUTION

THREE X 2 FL. oz (60 mL) Bottles

**HAIR REGROWTH TREATMENT**

**FOLIGAIN<sup>®</sup> Extra Strength Minoxidil** is for men who have experienced general thinning of hair at the top of their scalp (vertex only, as shown below). This product is not intended for frontal baldness or a receding hairline.

**FOLIGAIN<sup>®</sup> Extra Strength Minoxidil** for men has been shown to regrow men's hair with the following degrees of thinning hair or hair loss:



VERTEX  
VERTEX  
VERTEX

If men have more hair loss or hair loss in a place other than shown above, **FOLIGAIN<sup>®</sup> Extra Strength Minoxidil** may not work.

**FOR BEST RESULTS: APPLY DIRECTLY TO THE SCALP TWICE DAILY.**

**Drug Facts**

**Active Ingredient**  
Minoxidil 5% w/v.....Hair regrowth treatment for men

**Purpose**  
Use to regrow hair on the scalp. (vertex only, see picture on side of carton)

**Warnings**  
For external use only. For use by women only. Flammable: Keep away from fire or flame.

**Do not use if you:**

- are a woman.
- have hair loss other than that shown on the side of this carton, because this product may not work for you.
- have sudden and/or patchy hair loss.
- do not know the reason for your hair loss.
- are under 18 years of age.
- have a red, inflamed, infected, irritated or painful-feeling scalp.
- 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 you experience:**

- chest pain, rapid heartbeat, faintness, or dizziness.
- sudden, unexplained weight gain.

**Drug Facts (continued)**

- swelling of the hands or feet.
- scalp irritation or redness.
- unwanted facial hair growth.
- no 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**

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Alcohol, Propylene Glycol, Purified Water.

**Questions or comments?**

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FOLIGAIN<sup>®</sup>  
PROFESSIONAL SERIES

EXTRA STRENGTH FOR MEN

# Minoxidil

TOPICAL SOLUTION USP, 5%

EXTRA STRENGTH Hair Regrowth Treatment

This Package Contains:



- Three 2 fl oz (60 mL) Bottles of FOLIGAIN<sup>®</sup> Extra Strength 5% Minoxidil (three 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.)

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NDC XXXX-XXX-XX

**FOLIGAIN<sup>®</sup>**  
PROFESSIONAL SERIES

EXTRA STRENGTH FOR MEN

# Minoxidil

TOPICAL SOLUTION USP, 5%

CLINICALLY PROVEN TO HELP REGROW HAIR

**ONE MONTH SUPPLY**

**HAIR REGROWTH TREATMENT**

TOPICAL SOLUTION UNSCENTED

**Active Ingredient**  
Minoxidil 5% w/v  
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 • have no family history of hair loss • experience sudden and/or patchy hair loss • do not know the reason for your hair loss • are under 18 years of age • have a red, inflamed, infected, irritated, or painful feeling scalp • 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 you experience** • chest pain, rapid heartbeat, faintness, or dizziness • sudden, unexplained weight gain • swelling of the hands or feet • scalp irritation or redness • unwanted facial hair growth • no 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**

- Apply 1 mL two (2) times a day directly onto the scalp in the hair loss area • See enclosed leaflet for complete directions for use • Using more product, or using product 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 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
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**Manufactured for FOLIGAIN<sup>®</sup>**  
2625 S. 16th Street,  
Phoenix, AZ 85034 USA

#16497 • C26

**2 FL. oz (60 mL)**

# FOLIGAN

**Minoxidil**  
TOPICAL SOLUTION USP, 5%  
EXTRA STRENGTH

HAIR REGROWTH TREATMENT FOR MEN

UNSCENTED

Usage Guide and Consumer Information

## ENGLISH

Carefully save this leaflet for future reference.

**Read before you begin.** To achieve optimal results, you must use the product for up to 2 months, applying twice daily. For some men, it may be necessary to use this product for at least 4 months before seeing results.

Please read this leaflet carefully. This will help you understand how to use FOLIGAN and what to expect when using it. If you have any questions after reading this leaflet or if you still have questions, you should contact your healthcare professional at 1-844-473-7279. You can also visit our website at [www.foligan.com](http://www.foligan.com).

**What is FOLIGAN Minoxidil for men?** FOLIGAN Minoxidil is a topical liquid medication containing 5% minoxidil for exclusive use on the scalp and helps promote hair growth in men.

**Why use FOLIGAN Minoxidil for men?** FOLIGAN Minoxidil is specifically formulated for men. FOLIGAN Minoxidil may be appropriate for you if you are a man over 18 years of age suffering from thinning or progressive hair loss on the top of the scalp or at the vertex, as shown in the illustration below. It is not intended for frontal baldness or receding hairline. The process of cosmetic hair loss or thinning begins at the crown and recedes backward. If it has occurred gradually over the years, FOLIGAN Minoxidil will not work with or around the beginning of the vertex of the scalp. FOLIGAN Minoxidil is not intended for use on the crown or the crown shown below. In case of advanced hair loss, FOLIGAN Minoxidil may not work.



Many people who experience hair loss have other health problems with a similar history. If you do not have a family history of genetic hair thinning or progressive hair loss, or if your hair loss is frequent, consult your doctor.

**Who should NOT use FOLIGAN Minoxidil for men?** FOLIGAN Minoxidil should be avoided in men who have had a heart attack, stroke, or other cardiovascular disease. It should also be avoided in men who have had a heart attack, stroke, or other cardiovascular disease within the last 6 months.

**How does FOLIGAN Minoxidil for men work?** FOLIGAN Minoxidil is a topical liquid medication containing 5% minoxidil for exclusive use on the scalp and helps promote hair growth in men.

**How long should I use FOLIGAN Minoxidil for men?** Since hair generally grows only 1/2 to 1 inch (1.3 to 2.5 cm) per month, new hair growth with FOLIGAN Minoxidil also takes time to appear. Results may be seen in 2 months if used consistently. For some men, it may take up to 4 months to see results. If you do not see any results after 4 months, stop using FOLIGAN Minoxidil. When starting to use FOLIGAN Minoxidil, you may experience a temporary loss of hair for a few weeks. This is due to the fact that FOLIGAN Minoxidil causes hair to shed more quickly. This temporary increase in hair loss may occur at any time of the process by which FOLIGAN Minoxidil helps hair regrow. Thinning that occurs at the increased hair loss is temporary. If it continues after 4 months, consult your doctor.

**FOLIGAN Minoxidil for men works, what will the hair look like?** At first, hair growth is usually soft, wavy, and covers the scalp more thickly. After prolonged use, the hair should resemble the same color and thickness as the other hair on the scalp.

**How long will I have to use FOLIGAN Minoxidil for men?** You will experience new hair growth. It is important to continue using FOLIGAN Minoxidil; otherwise, hair loss will begin again. During studies with FOLIGAN Minoxidil, hair regrowth had not resumed to baseline after 48 weeks of continuous treatment but began again if treatment was resumed.

**What if I stop using FOLIGAN Minoxidil for men? Will I lose my hair?** Continuous use of FOLIGAN Minoxidil is necessary to maintain new hair growth. If you stop using FOLIGAN Minoxidil, you will lose the hair you have grown.

**How do I use FOLIGAN Minoxidil for men?** For best results, minoxidil applied 1 mL with the applicator twice daily, directly onto the scalp, in the areas of thinning, along more than the recommended dose will not improve results. Each bottle contains 1.5 mL of minoxidil. Use the applicator to apply the minoxidil. Always FOLIGAN Minoxidil by completely, before wearing a hat or wearing your head or a pillow, etc. FOLIGAN Minoxidil may cause stinging or itching. If it remains on the scalp, when applying FOLIGAN Minoxidil, you will lose the hair you have grown.

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**What to do if I use the product in forgotten or skipped?** Do not forget to apply one or two daily doses of FOLIGAN Minoxidil; you should continue with the next dose. Do not administer the missing dose.

**Can I use FOLIGAN Minoxidil for men twice daily? Will it be more effective?** No. FOLIGAN Minoxidil will not be more effective or better if applications than twice a day. Careful studies have been conducted to determine the appropriate amount of FOLIGAN Minoxidil to obtain the best results. More frequent use or exceeding the dose will not be shown to accelerate hair growth and may increase the risk of side effects.

**What type of shampoo should I use with FOLIGAN Minoxidil for men?** If you clean your hair before applying this product, use a mild shampoo.

**Can I use spray, foam, conditioners, gel, etc.?** Yes, your choice of styling products can be used on the hair while using FOLIGAN Minoxidil. For best results, FOLIGAN Minoxidil should be applied to the scalp before using any styling products. Establish a consistent FOLIGAN Minoxidil, your styling product, and your hair care routine. Use styling products as usual. Please note that the best results will be obtained with the use of FOLIGAN Minoxidil.

**Can I dye my hair, get a perm, or use hair relaxers while using the product?** Yes. We do not have evidence that dyeing, hair, getting a perm, or using hair relaxers changes the effect of FOLIGAN Minoxidil. However, dyeing and perming can cause scalp irritation in some people.

**How to use FOLIGAN Minoxidil for men?** FOLIGAN Minoxidil has been tested and found to be safe and effective when used as directed. FOLIGAN Minoxidil has been tested and found to be safe and effective when used as directed. FOLIGAN Minoxidil has been tested and found to be safe and effective when used as directed.

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**What type of shampoo should I use with FOLIGAN Minoxidil for men?** If you clean your hair before applying this product, use a mild shampoo.

Some people may need to use this product for almost 4 months before seeing results.

The amount of hair growth varies from person to person. This product does not work for all men.

**Stop use and seek your doctor's:**

• If you experience chest pain, dizziness, fainting, or dizziness.

• If you notice and increase weight gain occurs.

• Swelling occurs in the hands and feet.

• Sudden redness or redness occurs.

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# FOLIGAIN PROFESSIONAL SERIES EXTRA STRENGTH FOR MEN MINOXIDIL HAIR REGROWTH TREATMENT

minoxidil solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69607-9540
<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	50 mg in 1 mL

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69607-9540-0	3 in 1 BOX	05/05/2026	
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	05/05/2026	

**Labeler** - WR Group, Inc. (089173699)

**Registrant** - Pure Source, LLC (080354456)

Revised: 5/2026

WR Group, Inc.