

Drug Facts

Active ingredient

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

Purpose**Use** to regrow hair on the top of the scalp (vertex only, see pictures 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 booklet
- 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 with 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?**

- call toll-free 800-764-2463 or 215-273-8755 (collect)
- visit www.rogaine.com

Men's ROGAINE® Extra Strength 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. Men's ROGAINE® Extra Strength has been shown to regrow hair in men 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 different than shown above, Men's ROGAINE® Extra Strength may not work.



#1 DERMATOLOGIST RECOMMENDED BRAND

NEW LOOK

MEN'S Rogaine®

EXTRA STRENGTH

5% Minoxidil Topical Solution Hair Regrowth Treatment

REACTIVATES HAIR FOLLICLES TO STIMULATE REGROWTH

Topical Solution

CLINICALLY PROVEN TO HELP REGROW HAIR

UNSCENTED

Not For Use By Women

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

THIS PACKAGE CONTAINS

- One 60 mL (2 fl oz) Bottle of Men's ROGAINE® Extra Strength (one month supply)
- One child-resistant dropper applicator
- Information booklet with complete directions on how to use and obtain best results

Dist: Johnson & Johnson Healthcare Products Division of McNEIL-PPC, Inc. Skillman, NJ 08558 USA
Active Made in Italy
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Drug Facts

Active ingredient
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Warnings
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Flammable: Keep away from fire or flame

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■ 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.
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When using this product
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Drug Facts (continued)

May be harmful if used when pregnant or breast-feeding.
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Directions
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NEW LOOK

MEN'S Rogaine® EXTRA STRENGTH

5% Minoxidil Topical Solution Hair Regrowth Treatment

REACTIVATES HAIR FOLLICLES TO STIMULATE REGROWTH

Topical Solution

CLINICALLY PROVEN TO HELP REGROW HAIR UNSCENTED

Not For Use By Women



Three Month Supply • Three 60 mL (2 fl oz) Bottles

THIS PACKAGE CONTAINS



- Three 60 mL (2 fl oz) Bottles of Men's ROGAINE® Extra Strength (three month supply)
- One child-resistant dropper applicator
- Information booklet with complete directions on how to use and obtain best results

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MEN'S
Rogaine[®]
EXTRA STRENGTH

5% MINOXIDIL
TOPICAL SOLUTION

HAIR REGROWTH
TREATMENT



TOPICAL
SOLUTION



UNSCENTED

One Month Supply 60 mL (2 fl oz)

Read and keep carton and booklet 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

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- 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.
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- you use other medicines on the scalp

Ask a doctor before use if you have heart disease

When using this product

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- 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

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- your hands or feet swell
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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 inner carton and enclosed booklet for complete directions**
- using more or more often will not improve results
- continued use is necessary or hair loss will begin again

Inactive ingredients

alcohol, propylene glycol, purified water

Questions? call toll-free **800-764-2463** or **215-273-8755** (collect) visit www.rogaine.com

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



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IMPORTANT INFORMATION ABOUT

MEN'S
Rogaine[®]
EXTRA STRENGTH

5% MINOXIDIL
TOPICAL SOLUTION
HAIR REGROWTH
TREATMENT

REACTIVATES
HAIR FOLLICLES TO
STIMULATE REGROWTH



TOPICAL SOLUTION

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CLINICALLY PROVEN TO HELP REGROW HAIR
UNSCENTED

Not For Use By Women

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MEN'S Rogaine® EXTRA STRENGTH

5% MINOXIDIL TOPICAL SOLUTION

HAIR REGROWTH TREATMENT

UNSCENTED

Save this booklet 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 booklet carefully. It will help you understand how to use ROGAINE® Extra Strength Solution and what to expect from its use. If you have any questions after reading this booklet, or anytime while using ROGAINE® Extra Strength, you should ask your health care professional or call toll-free **800-764-2463** or **215-273-8755** (collect) visit www.rogaine.com

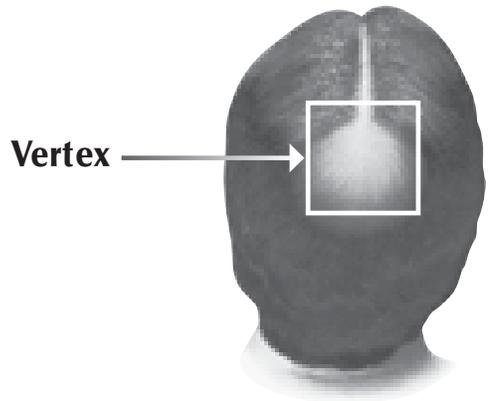
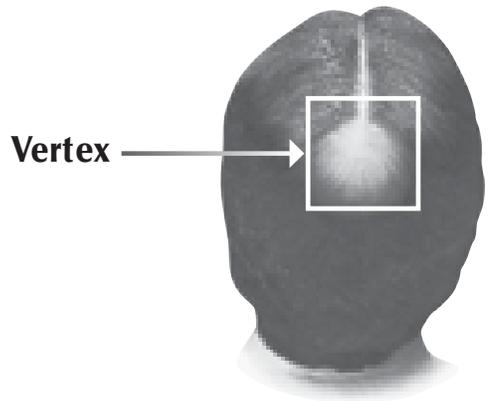
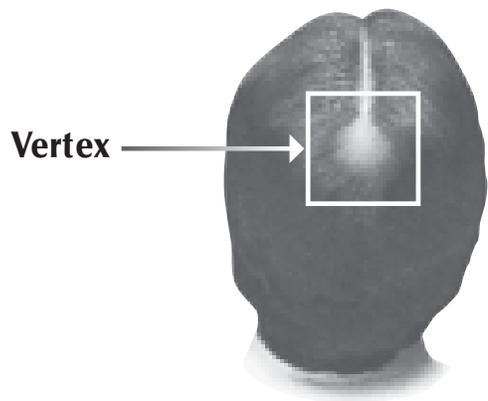
What is Men's ROGAINE® Extra Strength Solution?

ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution?

ROGAINE® Extra Strength Solution is for use only by men. ROGAINE® Extra Strength Solution 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 next page). 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.

ROGAINE® Extra Strength Solution is for men with hair loss or thinning hair that begins on the vertex of the scalp. ROGAINE® Extra Strength Solution is more likely to regrow hair in men with hair loss in the range shown on the next page. If men have more hair loss than shown, ROGAINE® 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 ROGAINE® Extra Strength Solution?

- Women should not use ROGAINE® Extra Strength Solution because studies have shown it works no better in women than Women's ROGAINE®. Some women may also grow facial hair. In addition, ROGAINE® Extra Strength Solution may be harmful if used during pregnancy or breast-feeding.
- ROGAINE® Extra Strength Solution should not be used on babies or for children under 18 years old.
- ROGAINE® Extra Strength Solution 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, ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to ROGAINE® Extra Strength Solution. The response to ROGAINE® Extra Strength Solution cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

However, to see your best results with ROGAINE® Extra Strength Solution, 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 ROGAINE® Extra Strength Solution may not work.

How soon can I expect results from using Men's ROGAINE® Extra Strength Solution?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution.

When you **first** begin to use ROGAINE® Extra Strength Solution, 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 ROGAINE® Extra Strength Solution regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If Men’s ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution?

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

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What happens if I completely stop using Men's ROGAINE® Extra Strength Solution? Will I keep the new hair?

Continuous use of ROGAINE® Extra Strength Solution is needed to maintain hair regrowth.

If you stop using ROGAINE® Extra Strength Solution, you will lose your newly regrown hair in 3 to 4 months.

How do I use Men's ROGAINE® Extra Strength Solution?

For best results, apply 1 mL with applicator **2 times a day directly onto the scalp** in the hair loss area. Using more or using more often will not improve results. Each bottle should last one month, if used as directed.

Allow time for ROGAINE® Extra Strength Solution to dry completely before wearing a hat, or lying on a pillow, etc. ROGAINE® Extra Strength Solution may cause staining of clothing or linens if damp on the scalp. When applying ROGAINE® Extra Strength Solution 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.

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**When do I use Men's ROGAINE®
Extra Strength Solution?**

Apply ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution?**

If you miss one or two daily doses of ROGAINE® Extra Strength Solution, just continue with your next dose. You should not make up for missed doses.

**Can I use Men's ROGAINE® Extra Strength
Solution more than twice a day? Will it work
faster, better?**

No. ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution?

If you wash your scalp before applying ROGAINE® Extra Strength Solution, 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 ROGAINE® Extra Strength Solution. For best results, ROGAINE® Extra Strength Solution should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of ROGAINE® Extra Strength Solution. However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we recommend the following precautions:

- 1.** To avoid possible scalp irritation, you should make sure all of the ROGAINE® Extra Strength Solution has been washed off the hair and scalp before using color or perm chemicals.
- 2.** For best results, do not apply ROGAINE® Extra Strength Solution on the same day that you use a chemical treatment on your hair.
- 3.** Do not use ROGAINE® Extra Strength Solution 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 ROGAINE® Extra Strength Solution as usual.
- 4.** Simply restart your normal ROGAINE® Extra Strength Solution routine. There is no need to use more ROGAINE® Extra Strength Solution to make up for missed applications. Missing one day of ROGAINE® Extra Strength Solution will not affect your hair regrowth results.

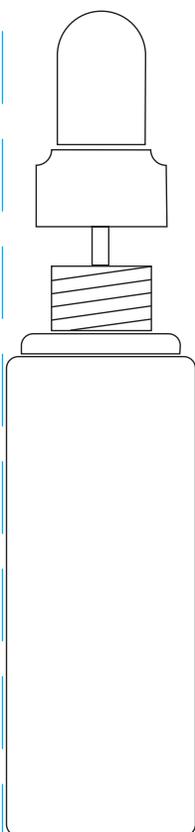
Can I apply Men's ROGAINE® Extra Strength Solution and wash my hair an hour later?

No. For ROGAINE® Extra Strength Solution to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Directions for Use

- 1.** Remove the overcap.
- 2.** Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
- 3.** Part your hair in the area of hair thinning/loss. Follow the instructions shown on the next page 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 1 month, if used as directed. Use a mild shampoo if you wash your scalp before applying ROGAINE® Extra Strength.

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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.

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 page 3 of this booklet 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

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- scalp irritation or redness occurs
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- 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 ROGAINE® Extra Strength Solution?

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. ROGAINE® Extra Strength Solution contains alcohol, which will cause burning or irritation of the eyes. If ROGAINE® Extra Strength Solution accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Men's ROGAINE® Extra Strength Solution 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 using ROGAINE® Extra Strength Solution. Over time, the unwanted hair, if caused by ROGAINE® Extra Strength Solution, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

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

Can I use Men's ROGAINE® Extra Strength Solution for baldness or hair loss in babies or children?

No. ROGAINE® Extra Strength Solution 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 **800-764-2463** or **215-273-8755** (collect) visit www.rogaine.com

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