GOOD SENSE HAIR REGROWTH TREATMENT- minoxidil solution
L. Perrigo Company

Perrigo Hair Regrowth Treatment 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 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. Minoxidil topical solution 5% 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. (1-800-222-1222)

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 minoxidil topical solution 5% for men
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%
- store at 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients

alcohol, propylene glycol, purified water

Questions or comments?

1-800-719-9260

Consumer Information

IMPORTANT INFORMATION ABOUT

Minoxidil Topical Solution USP 5%

Hair Regrowth Treatment

UNSCENTED

Extra Strength For Men

- **Clinically Proven to Help Regrow Hair**
- **Reactivates Hair Follicles To Stimulate Regrowth**
- **Provides more hair regrowth than minoxidil topical solution 2%**

Not For Use By Women

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 minoxidil topical solution 5% and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using minoxidil topical solution 5%, you should ask your healthcare professional or call us at 1-800-719-9260.

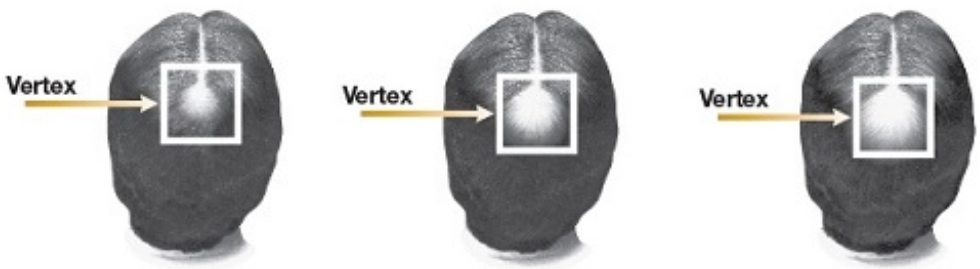
What is minoxidil topical solution 5%?

Minoxidil topical solution 5% is a clear, light amber liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use minoxidil topical solution 5%?

Minoxidil topical solution 5% is for use only by men. Minoxidil topical solution 5% 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 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.

Minoxidil topical solution 5% is for men with hair loss or thinning hair that begins on the vertex of the scalp. Minoxidil topical solution 5% is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, minoxidil topical solution 5% 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 minoxidil topical solution 5%?

- Women should not use minoxidil topical solution 5% because studies have shown it works no better in women than minoxidil topical solution 2%. Some women may also grow facial hair. In addition, minoxidil topical solution 5% may be harmful if used during pregnancy or breast-feeding.
- Minoxidil topical solution 5% should not be used on babies or for children under 18 years old.
- Minoxidil topical solution 5% 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, minoxidil topical solution 5% 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 minoxidil topical solution 5% work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to minoxidil topical solution 5%. The response to minoxidil topical solution 5% cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

However, to see your best results with minoxidil topical solution 5%, 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 minoxidil topical solution 5% may not work.

How soon can I expect results from using minoxidil topical solution 5%?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with minoxidil topical solution 5% 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 minoxidil topical solution 5%.

When you **first** begin to use minoxidil topical solution 5%, 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 minoxidil topical solution 5% regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If minoxidil topical solution 5% 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 minoxidil topical solution 5%?

If you experience hair regrowth, continued use of minoxidil topical solution 5% is necessary or the hair loss will begin again. In studies with minoxidil topical solution 5%, 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 minoxidil topical solution 5%?

Will I keep the new hair?

Continuous use of minoxidil topical solution 5% is needed to maintain hair regrowth.

If you stop using minoxidil topical solution 5%, you will lose your newly regrown hair in 3 to 4 months.

How do I use minoxidil topical solution 5%?

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 minoxidil topical solution 5% to dry completely before wearing a hat, or lying on a pillow, etc. Minoxidil topical solution 5% may cause staining of clothing or linens if damp on the scalp. When applying minoxidil topical solution 5% 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 minoxidil topical solution 5%?

Apply minoxidil topical solution 5% 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 minoxidil topical solution 5%?

If you miss one or two daily doses of minoxidil topical solution 5%, just continue with your next dose. You should not make up for missed doses.

Can I use minoxidil topical solution 5% more than twice a day? Will it work faster, better?

No. Minoxidil topical solution 5% 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 5% 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 minoxidil topical solution 5%?

If you wash your scalp before applying minoxidil topical solution 5%, 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 minoxidil topical solution 5%. For best results, minoxidil topical solution 5% should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying minoxidil topical solution 5% 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 minoxidil topical solution 5%?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of minoxidil topical solution 5%. 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 minoxidil topical solution 5% has been washed off the hair and scalp before using color or perm chemicals.
2) For best results, do not apply minoxidil topical solution 5% on the same day that you use a chemical treatment on your hair.
3) Do not use minoxidil topical solution 5% 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 minoxidil topical solution 5% as usual.
4) Simply restart your normal minoxidil topical solution 5% routine. There is no need to use more minoxidil topical solution 5% to make up for missed applications. Missing one day of minoxidil topical solution 5% will not affect your hair regrowth results.

Can I apply minoxidil topical solution 5% and wash my hair an hour later?

No. For minoxidil topical solution 5% to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Directions for Use

1) Remove the 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 minoxidil topical solution 5%.

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 the other side of this leaflet or your hair loss is on the front of the scalp. Minoxidil topical solution 5% 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. (1-800-222-1222)

What are the most common side effects with minoxidil topical solution 5%?

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. Minoxidil topical solution 5% contains alcohol, which will cause burning or irritation of the eyes. If minoxidil topical solution 5% accidentally gets into eyes, rinse with large amounts of cool tap water.

Can minoxidil topical solution 5% 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 minoxidil topical solution 5%. Over time, the unwanted hair, if caused by minoxidil topical solution 5%, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

1) limit the application of minoxidil topical solution 5% only to the scalp;
2) if you use your hands to apply minoxidil topical solution 5%, wash your hands well immediately afterwards; and
3) after your nighttime application of minoxidil topical solution 5%, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use minoxidil topical solution 5% for baldness or hair loss in babies or children?

No. Minoxidil topical solution 5% must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your healthcare professional or call us at 1-800-719-9260.

Store at 20º to 25ºC (68º to 77ºF). Keep tightly closed.

Packaged By

Perrigo®

Allegan, MI 49010

Rev 10-19

32J0000J1

Package/Label Principal Display Panel

GOODSENSE®

Extra Strength

Minoxidil Topical Solution USP, 5%

Hair Regrowth Treatment For Men

Clinically Proven to Help Regrow Hair

REACTIVATES Hair Follicles to Stimulate Regrowth

Topical Solution

#1 Dermatologist Recommended Active Ingredient

Three Month Supply

Unscented

Not For Use By Women

Compare to active ingredient of Men’s Rogaine® Extra Strength

3-2 FL OZ (60 mL) BOTTLES

TOTAL 6 FL OZ (180 mL)

GOOD SENSE HAIR REGROWTH TREATMENT

minoxidil solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0113-1032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 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:0113-1032-30	3 in 1 CARTON	05/25/2021	
1	NDC:0113-1032-16	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:0113-1032-40	6 in 1 CARTON	07/29/2021	
2	NDC:0113-1032-16	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	ANDA075598	05/25/2021	

Labeler - L. Perrigo Company (006013346)

Revised: 8/2026 L. Perrigo Company