

MINOXIDIL - minoxidil solution
Physicians Total Care, Inc.

Minoxidil Topical Solution 2% (For Men)

ACTIVE INGREDIENT

Minoxidil 2% w/v

PURPOSE

Hair regrowth treatment

USE

To regrow hair on the top of the scalp (vertex only, see pictures on side of carton)

WARNINGS

For external use only

Flammable: Keep away from fire or flame

DO NOT USE IF

- your degree of hair loss is more than that shown on the side of this carton, because this product may not work for you
- 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. You may need to use this product 2 times a day 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 everyone.

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

PREGNANCY OR BREAST-FEEDING

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

- part your hair and apply one mL 2 times a day directly onto the scalp in the area of hair thinning/loss
- 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 this carton. It contains important information.
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, the following response to minoxidil topical solution 2% for men was reported: 26% of men reported moderate to dense hair regrowth after using minoxidil topical solution 2% for men for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).
- store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

INACTIVE INGREDIENTS

Alcohol (60% v/v), propylene glycol, purified water

QUESTIONS

1-800-432-8534 (select option #2)

This Package Contains:

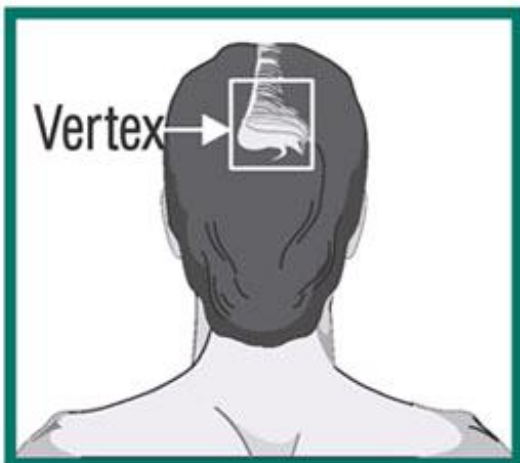
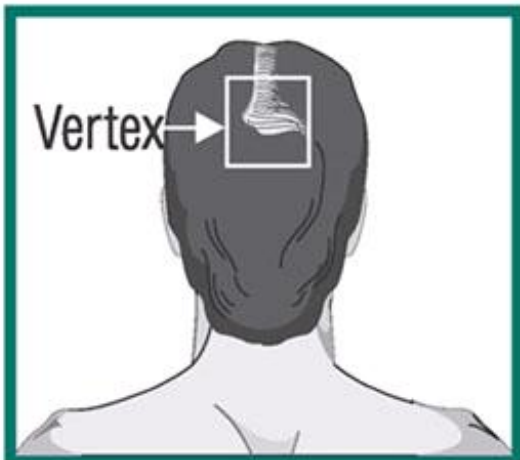
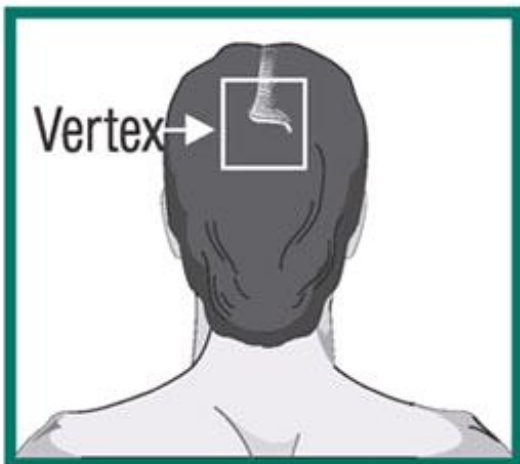
- One 60 mL (2 fl oz) bottle of Minoxidil Topical Solution 2% (one month supply)
- One child-resistant dropper applicator
- Information leaflet on how to use and obtain best results

Using the Dropper Applicator:

1. Remove cap by pushing and turning in direction of the arrows on the cap
2. 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.
3. Place the tip 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.
4. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until

tightly closed.

Minoxidil Topical Solution is for men who have a general thinning of hair on the top of the scalp (vertex) as shown. Minoxidil Topical Solution has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss than shown above, Minoxidil Topical Solution may not work.

*This product is not affiliated with, manufactured by, or produced by the makers of Rogaine®.

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Distributed by:

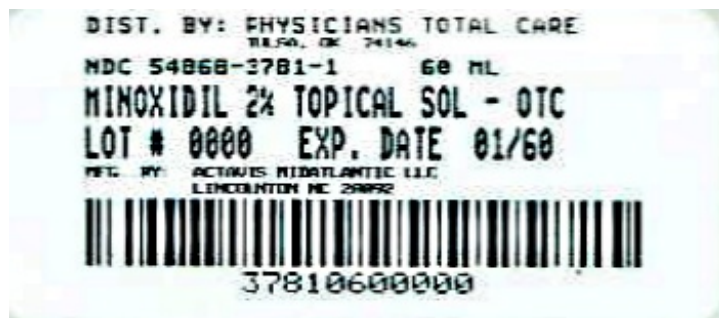
Actavis Mid Atlantic LLC
1877 Kawai Road
Lincolnton, NC 28092 USA

Made in Canada

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Men's Rogaine®*
Regular Strength FOR MEN
HAIR REGROWTH TREATMENT
Minoxidil Topical Solution USP 2%
Clinically Proven to Help Regrow Hair
Revitalizes Hair Follicles
ONE MONTH SUPPLY 1-60 mL (2 fl oz) Bottle



ONE MONTH SUPPLY CARTON LABEL

CONSUMER INFORMATION

MINOXIDIL TOPICAL SOLUTION USP 2%

Important information about – Minoxidil Topical Solution USP 2% for Men

Save leaflet for future reference.

- Hair regrowth treatment

Minoxidil Topical Solution contains the only ingredient available without a prescription that is medically proven effective to help regrow hair.

Please read this leaflet carefully. It will help you understand how to use Minoxidil Topical Solution and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Minoxidil Topical Solution, you should ask your health care professional.

What is Minoxidil Topical Solution?

Minoxidil Topical Solution is a clear to pale yellow liquid medication for use only on the scalp to help

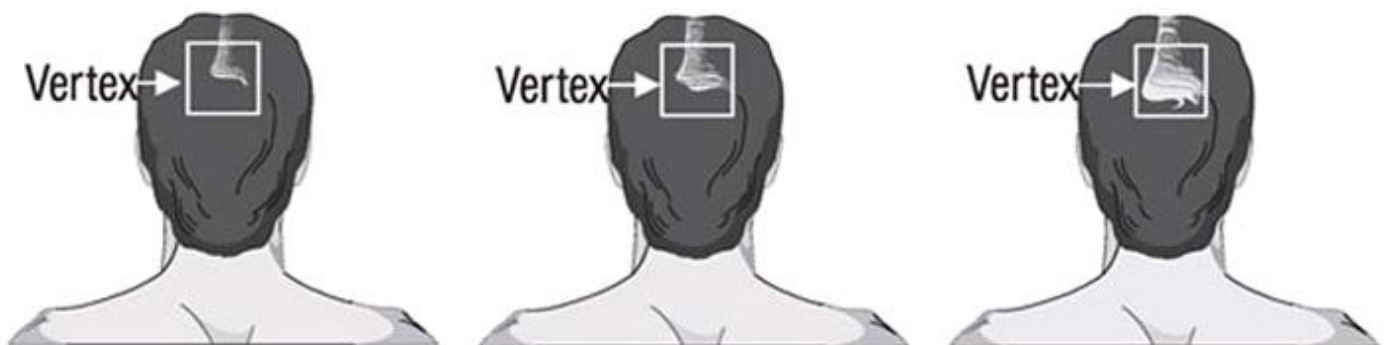
regrow hair.

Who may use Minoxidil Topical Solution?

Minoxidil Topical Solution may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Minoxidil Topical Solution is for men with hair loss or thinning that begins at the top of the scalp (vertex) as shown below. Frontal hair growth has not been demonstrated in clinical trials. Minoxidil Topical Solution 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 may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.**



Who should NOT use Minoxidil Topical Solution?

Minoxidil Topical 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; excessive vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Minoxidil Topical 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.

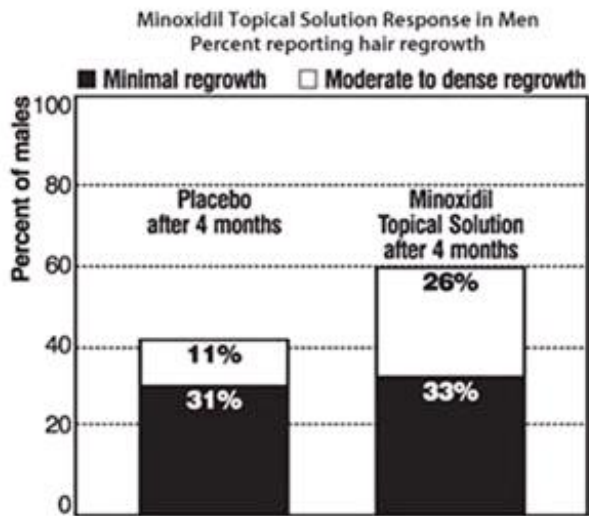
You should ask your doctor if you are unsure of the cause for your hair loss.

Will Minoxidil Topical Solution work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Minoxidil Topical Solution. The response to Minoxidil Topical Solution cannot be predicted. No one will be able to grow back all their hair.

You may respond better if you have been losing your hair for a short period of time or have little initial hair loss.

In clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, the following response of Minoxidil Topical Solution was reported:



26% of men reported moderate to dense hair regrowth after using Minoxidil Topical Solution for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).

What Minimal, Moderate and Dense Hair Regrowth Will Mean For You			
	Minimal	Moderate	Dense
Number of Hairs	Some new hairs are seen, but not enough to cover thinning areas.	New hairs cover some or all of thinning areas.	New hairs cover, or almost completely cover, thinning areas.
Hair Density	Hairs in thinning areas do not grow as closely together as hairs on the rest of the head.	Hairs in thinning areas grow more closely together, but are not as close together as hairs on the rest of the head.	Hairs in thinning areas grow as closely together as hairs on the rest of the head.

Can Minoxidil Topical Solution be used to prevent hair loss?

We do not know if Minoxidil Topical Solution will prevent hair loss.

How soon can I expect results from using Minoxidil Topical Solution?

Since normal hair usually grows only ½ to 1 inch per month, hair regrowth with Minoxidil Topical Solution also takes time. Generally new hair growth is slow for a Minoxidil Topical Solution user. Continued use 2 times a day for at least 4 months is usually needed before you notice hair regrowth.

If you do not see hair regrowth in 4 months, stop using Minoxidil Topical Solution and see your doctor.

When you first begin to use Minoxidil Topical Solution, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

If Minoxidil Topical Solution is working, what will the hair look like?

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hair should be the same color and thickness as the other hairs on your scalp.

How long do I need to use Minoxidil Topical Solution?

If you respond to Minoxidil Topical Solution, you will need to use it 2 times a day to keep and continue the hair regrowth. Up to 12 months of use may be needed to see your best results from Minoxidil Topical Solution.

What happens if I completely stop using Minoxidil Topical Solution? Will I keep the new hair?

Continuous use of Minoxidil Topical Solution is needed to maintain hair regrowth. If you stop using Minoxidil Topical Solution, the normal hair loss process will start again. You will probably lose your

newly regrown hair in three to four months.

What is the dosage of Minoxidil Topical Solution?

You should apply a dose (1 mL) of Minoxidil Topical Solution directly onto the scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please refer to the “Directions for Use” section of this leaflet.

What if I miss a dose or forget to use Minoxidil Topical Solution?

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

Can I use Minoxidil Topical Solution more than two times a day?

Will it work faster, better?

No. Minoxidil Topical Solution will not work faster or better if used more than 2 times a day. Studies have been carefully conducted to determine the correct amount of Minoxidil Topical 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 are the most common side effects with Minoxidil Topical Solution?

The most common side effects are itching and other skin irritations of the treated area of the scalp. Minoxidil Topical Solution contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Minoxidil Topical Solution accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

What kind of shampoo should I use with Minoxidil Topical Solution?

If you wash your scalp before applying Minoxidil Topical Solution, use a mild shampoo.

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

Yes. There is no need to change your usual hair care routine when using Minoxidil Topical Solution. However, you should apply Minoxidil Topical Solution first and wait for it to dry before applying your styling aids.

Can I have my hair colored or permed or use hair relaxers while using Minoxidil Topical Solution?

Yes. We have no information that these treatments change the effect of Minoxidil Topical Solution. However, to avoid possible scalp irritation, you should make sure all of the Minoxidil Topical Solution has been washed out of the hair and scalp before using these chemicals.

Can I apply Minoxidil Topical Solution and wash my hair an hour later?

No. For Minoxidil Topical Solution to work best, you should allow Minoxidil Topical Solution to remain on the scalp for about 4 hours before washing.

Can I go swimming or out in the rain?

Yes. Avoid washing off the Minoxidil Topical Solution. If possible, apply 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 Minoxidil Topical Solution.

Can Minoxidil Topical Solution produce unwanted hair?

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Minoxidil Topical Solution to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Minoxidil Topical Solution.

If you experience unwanted hair, discontinue using Minoxidil Topical Solution and see your doctor for recommendations about appropriate treatment. After stopping use of Minoxidil Topical Solution, the unwanted hair, if caused by the use of Minoxidil Topical Solution, should go away over time.

You can take steps to decrease the chances of unwanted hair growth: 1) limit the application of Minoxidil Topical Solution only to the scalp; 2) if you use your hands to apply Minoxidil Topical Solution, wash your hands thoroughly afterwards; and 3) allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Minoxidil Topical Solution.

Can I use Minoxidil Topical Solution for baldness or hair loss in babies and children?

No. Minoxidil Topical Solution must not be used to treat baldness or hair loss in babies or children.

Are there any special warnings about the use of Minoxidil Topical Solution?

For external use only

Flammable: Keep away from fire or flame

Do not use if

- your degree of hair loss is more than that shown on the front of this leaflet, because this product may not work for you.
- 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. You may need to use this product 2 times a day 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 everyone.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What factors may increase the risk of serious side effects with Minoxidil Topical Solution?

Minoxidil Topical Solution should be applied only to the scalp. The risk of side effects may be greater when it is applied to other parts of the body.

Directions for Use

1. Remove the cap. To remove, push down and turn in direction of the arrows on the cap.

- 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.

Using the Dropper Applicator



- 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.
- Next, place the tip 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.
- After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

If you have any other questions, ask your health care professional.

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

Save this leaflet for future reference.

Manufactured by: Contract Pharmaceuticals Ltd.

7600 Danbro Crescent

Mississauga, ON

Canada, L5N 6L6

For: Actavis Mid Atlantic LLC

1877 Kawai Road

Lincolnton, NC 28092 USA

FORM NO. 0066 Rev. 1/08

2004373 VC3043

MINOXIDIL			
minoxidil solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-3781(NDC:0472-0066)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MINOXIDIL (UNII: 5965120 SH1) (MINOXIDIL - UNII:5965120 SH1)		MINOXIDIL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3781-1	1 in 1 CARTON		
1		60 mL in 1 BOTTLE		
2	NDC:54868-3781-0	2 in 1 CARTON		
2		60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074588	06/04/1996	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-3781)

Revised: 10/2012

Physicians Total Care, Inc.