BASIC CARE HAIR REGROWTH TREATMENT- minoxidil solution
Amazon.com Services LLC

Amazon Hair Regrowth Treatment Drug Facts

Active ingredient

Minoxidil 2% w/v

Purpose

Hair regrowth treatment

Use

to regrow hair on the scalp

Warnings

For external use only

Flammable: Keep away from fire or flame

Do not use if

- your degree of hair loss is different 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
- your hair loss is associated with childbirth
- 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

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.
- in clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- 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 2%

Hair Regrowth Treatment

UNSCENTED

For Women

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Minoxidil topical solution 2% contains the only ingredient that is medically proven effective to help regrow hair in women.

- **Clinically Proven to Help Regrow Hair**
- **Reactivates Hair Follicles To Stimulate Regrowth**
- **Previously Available Only by Prescription**

SAVE THIS LEAFLET FOR FUTURE REFERENCE

Please read this leaflet carefully. It will help you understand how to use minoxidil topical solution 2% and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using minoxidil topical solution 2%, you should ask your health care professional or call us at 1-800-719-9260.

What is minoxidil topical solution 2%?

Minoxidil topical solution 2% is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

Who may use minoxidil topical solution 2%?

Minoxidil topical solution 2% 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 2% is for general thinning of hair on the top of the scalp as shown below. Minoxidil topical solution 2% has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, minoxidil topical solution 2% 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 ispatchy, talk to your doctor**.

Who should NOT use minoxidil topical solution 2%?

Minoxidil topical solution 2% will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, minoxidil topical solution 2% 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 minoxidil topical solution 2% if hair loss is patchy as shown below.

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

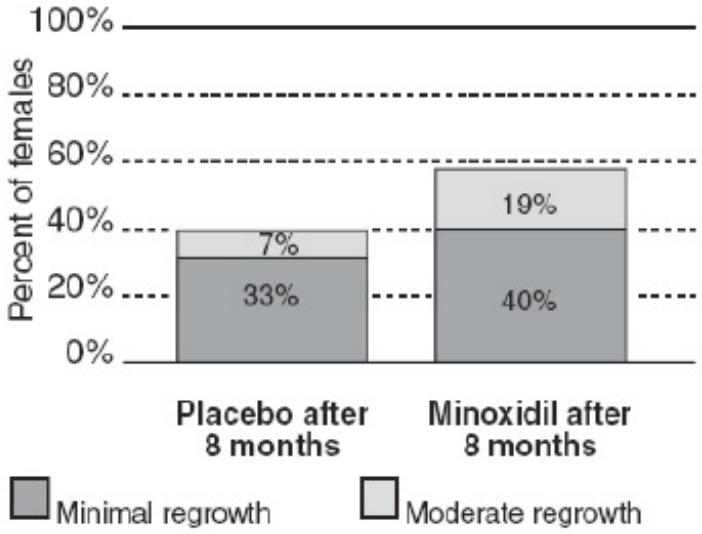
Will minoxidil topical solution 2% work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to minoxidil topical solution 2%. The response to minoxidil topical solution 2% cannot be predicted. No one will be able to grow back all their hair.

In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported:

FEMALE RESPONSE TO MINOXIDIL TOPICAL SOLUTION 2%

Percent reporting hair regrowth



19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

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.

Can minoxidil topical solution 2% be used to prevent hair loss?

We do not know if minoxidil topical solution 2% will prevent hair loss.

How soon can I expect results from using minoxidil topical solution 2%?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with minoxidil topical solution 2% also takes time. Generally new hair growth is slow for a minoxidil topical solution 2% user. Continued use of 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 2% and see your doctor.

When you first begin to use minoxidil topical solution 2%, 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 2% is working, what will the hair look like?

At first, hair growth may be soft, downy, colorless hairs. 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 2%?

If you respond to minoxidil topical solution 2%, you will need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from minoxidil topical solution 2%.

What happens if I completely stop using minoxidil topical solution 2%?

Will I keep the new hair?

Continuous use of minoxidil topical solution 2% is needed to maintain hair regrowth. If

you stop using minoxidil topical solution 2%, 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 2%?

You should apply a dose (1 mL) of minoxidil topical solution 2% 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 2%?

If you miss one or two daily doses of minoxidil topical solution 2%, just continue with your next dose. You should not make up for missed doses.

Can I use minoxidil topical solution 2% more than two times a day?

Will it work faster, better?

No. Minoxidil topical solution 2% 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 2% 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 chances of side effects.

What are the most common side effects with minoxidil topical solution 2%?

The most common side effects are itching and other skin irritations of the treated area of the scalp. Minoxidil topical solution 2% contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If minoxidil topical solution 2% 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 2%?

If you wash your scalp before applying minoxidil topical solution 2%, 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 2%. However, you should apply minoxidil topical solution 2% 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 2%?

Yes. We have no information that these treatments change the effect of minoxidil topical solution 2%. However, to avoid possible scalp irritation, you should make sure all of the minoxidil topical solution 2% has been washed off the hair and scalp before using these chemicals.

Can I apply minoxidil topical solution 2% and wash my hair an hour later?

No. For minoxidil topical solution 2% to work best, you should allow minoxidil topical solution 2% 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 2%. If possible, apply minoxidil topical solution 2% 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 2%.

Can minoxidil topical solution 2% 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 2% 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 2%.

If you experience unwanted hair, discontinue using minoxidil topical solution 2% and see your doctor for recommendations about appropriate treatment. After stopping use of minoxidil topical solution 2%, the unwanted hair, if caused by the use of minoxidil topical solution 2%, should go away over time.

You can take steps to decrease the chances for unwanted hair growth:

1) limit the application of minoxidil topical solution 2% only to the scalp,

2) if you use your hands to apply minoxidil topical solution 2%, 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 2%.

Can I use minoxidil topical solution 2% for baldness or hair loss in babies and children?

No. Minoxidil topical solution 2% 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 2%?

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 other side 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
- your hair loss is associated with childbirth
- 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
- scalp irritation or redness occurs
- sudden, unexplained weight gain occurs
- unwanted facial hair growth occurs
- your hands or feet swell
- 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 factors may increase the risk of serious side effects with minoxidil topical solution 2%?

Minoxidil topical solution 2% 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.

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 2%.

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.

If you have any other questions, ask your health care professional or call 1-800-719-9260.

Store at 20º to 25ºC (68º to 77ºF)

Keep tightly closed.

Save this leaflet for future reference.

Packaged by

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Allegan, MI 49010

Rev 01-20

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Package/Label Principal Display Panel

amazon

basic care

For Women

Compare to Women’s Rogaine® active ingredient

Minoxidil Topical Solution USP, 2%

Hair Regrowth Treatment

Reactivates Hair Follicles To Stimulate Regrowth

Clinically Proven To Help Regrow Hair

Topical Solution

#1 Dermatologist Recommended Active Ingredient

Unscented

Three Month Supply

3-60 mL (2 FL OZ) BOTTLES

TOTAL 180 mL (6 FL OZ)

BASIC CARE HAIR REGROWTH TREATMENT

minoxidil solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72288-701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 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:72288-701-16	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/12/2022	
2	NDC:72288-701-30	3 in 1 CARTON	05/12/2022	
2		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	ANDA075357	05/12/2022	

Labeler - Amazon.com Services LLC (128990418)

Revised: 2/2024

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