

LOESCH HAIR REGROWTH FORMULA UNSCENTED TOPICAL SOLUTION REGULAR-STRENGTH FOR MEN AND WOMEN- minoxidil solution

Loesch Laboratory Consultant, INC.

Drug Facts

Active Ingredients

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 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 2% 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 or children.

Your scalp is red, inflamed, infected, irritated, or painful.

You use other medicines on the scalp.

ASK DOCTOR

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. Results may occur at 2 months with twice daily 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 everyone.

Stop use and ask a doctor if you have

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 immediately. (1-800-222-1222)

Directions

Apply one mL 2 times daily directly onto the scalp in the hair loss area.
Using more or more often will not improve results.
Continued use is necessary or hair loss will resume.

Other information

See hair loss picture on the side of this carton.
Before use, read all information on carton and printed insert.
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 2%.
In clinical studies with mostly caucasian women aged 18-45 years with mild to no 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. This compares with 7% of women reporting moderate hair regrowth and 33% reporting minimal regrowth after using the placebo, the liquid without minoxidil in it, for 8 months.

Inactive Ingredients

Alcohol, Propylene Glycol, Purified water

Questions or Comments?

1-800-237-7157

NDC 25280-007-42

Loesch®

HAIR REGROWTH FORMULA

Unscented Topical Solution

Regular-Strength
MINOXIDIL 2%

FOR **MEN & WOMEN**
FDA-Approved

- Clinically Proven to Help Regrow Hair
 - Revitalizes Hair Follicles
- One Month Supply 60 ml (2.0 fl. oz.)

Before use, read all information on carton and printed insert. Keep the carton. It contains important information.

Active ingredient: Minoxidil 2% w/v

Warnings

For external use only. Flammable: Keep away from fire or flame.

Do not use if

- 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 or 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.

Stop use and ask a doctor if you have

- 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 immediately. (1-800-222-1222)

Directions

- Apply one mL 2 times a day directly onto the scalp in the hair loss area.
- See carton for complete directions
- Using more or more often will not improve results.
- Continued use is necessary or hair loss will resume.

Inactive Ingredients: Alcohol, Propylene Glycol, Purified water.

Questions or Comments? 1-800-231-7157

Store at 20°-25°C (68°-77°F).

Keep tightly closed.

Distributed By:

Loesch Laboratory Consultants, Inc.
4311 South Dr.

Houston, Texas 77053-4820, USA

800-231-7157

M-F 8 am - 5 pm CST

www.loeschlab.com

NOT FOR RESALE

Drug Facts (Continued)

Directions

- Apply one mL 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 or hair loss will resume.

Other Information

- See hair loss picture on the side of this carton.
- Before use, read all information on carton and printed insert.
- 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 2%.
- In clinical studies with mostly caucasian 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 and 40% had minimal hair regrowth after using Minoxidil Topical Solution 2% for 8 months. This compares with 7% of women reporting moderate hair regrowth and 33% reporting minimal regrowth after using the placebo, the liquid without minoxidil in it, for 8 months.
- Store at 20-25C (68-77F). Keep tightly closed.

Inactive Ingredients: Alcohol, Propylene Glycol, Purified water

Questions or Comments?
1-800-231-7157

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Men's Rogaine® Extra Strength.

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NDC 25280-007-42

Loesch®

HAIR REGROWTH FORMULA

Unscented Topical Solution

Regular-Strength
MINOXIDIL 2%

FOR **MEN & WOMEN**

- Clinically Proven to Help Regrow Hair
- Revitalizes Hair Follicles

FDA-Approved

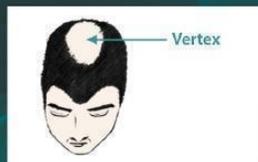
One Month Supply
60 ml (2.0 fl. oz.)

DIRECTIONS

Apply one mL 2 times a day directly onto the scalp in the hair loss area. See inside sleeve for complete directions. Using more or more often will not improve results. Continued use is necessary or hair loss will resume.

Minoxidil Topical Solution 2% is for men and women 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. Minoxidil Topical Solution 2% has been shown to regrow hair in people with the degree of hair loss shown in the images below.

If you have more hair loss or hair loss in a place different than shown below, Minoxidil Topical Solution 2% may not work.



THIS PACKAGE CONTAINS:

- One 60 ml. (2 oz.) bottle of Minoxidil Topical Solution USP 2% Regular-Strength (one month supply)
- One dropper applicator
- One printed sleeve with complete directions on how to use and obtain best results.

SEE INSIDE FOR ADDITIONAL INFORMATION

Drug Facts

Active ingredient	Purpose
Minoxidil 2% w/v	Hair Regrowth Treatment

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

Warnings

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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 or 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. Results may occur at 2 months with twice daily usage. For some people, 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 everyone.

- Stop use and ask a doctor if you have**
- 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 immediately. (1-800-222-1222)

REGULAR-STRENGTH FOR MEN AND WOMEN

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25280-007(NDC:49035-202)
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
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25280-007-42	1 in 1 PACKAGE	08/11/2014	
1		60 mL in 1 BOTTLE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075357	08/11/2014	

Labeler - Loesch Laboratory Consultant, INC. (026619510)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	relabel(25280-007)

Revised: 11/2019

Loesch Laboratory Consultant, INC.