

**LOESCH HAIR REGROWTH FORMULA UNSCENTED TOPICAL SOLUTION EXTRA-STRENGTH FOR MEN- minoxidil solution**

**Loesch Laboratory Consultant, INC.**

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**Drug Facts**

**Active Ingredients**

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. 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 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 5%.  
In clinical studies with mostly caucasian men aged 18-49 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% for men provided more hair growth than Minoxidil Topical Solution 2%.

**Inactive Ingredients**

Alcohol, Propylene Glycol, Purified water

**Questions or Comments?**

1-800-237-7157

NDC 25280-006-42

► **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 5% for men. ● In clinical studies with mostly caucasian men aged 18-49 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% for men provided more hair growth than Minoxidil Topical Solution 2%. ● Store at 20-25°C (68-77°F). Keep tightly closed.

**Inactive Ingredients:** Alcohol, Propylene Glycol, Purified water

**Questions or Comments?**  
1-800-231-7157

**THIS PACKAGE CONTAINS:**

- One 60 mL (2 oz.) bottle of Minoxidil Topical Solution USP 5% Extra Strength (one month supply)
- One dropper applicator
- One printed sleeve with complete directions on how to use and obtain best results

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

**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](http://www.loeschlab.com)

# Loesch®

## HAIR REGROWTH FORMULA

Unscented Topical Solution

### Extra-Strength MINOXIDIL 5% FOR MEN

■ Clinically Proven to Help Regrow Hair

■ Revitalizes Hair Follicles

FDA-Approved

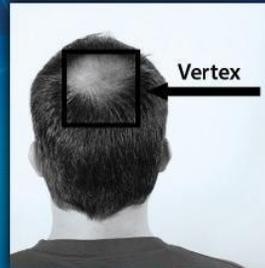
One Month Supply  
60 mL (2.0 fl. oz.)

**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 5% 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. Minoxidil Topical Solution 5% has been shown to regrow hair in men with the degree of hair loss shown in the image below.

If men have more hair loss or hair loss in a place different than shown below, Minoxidil Topical Solution 5% may not work.



SEE INSIDE FOR ADDITIONAL INFORMATION

**Drug Facts**

Active ingredient	Purpose
Minoxidil 5% w/v	Hair Regrowth Treatment For Men

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

NDC 25280-006-42

# Loesch®

## HAIR REGROWTH FORMULA Unscented Topical Solution

### Extra-Strength MINOXIDIL 5% FOR MEN 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 5% w/v

**Warnings**

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- You do not know the reason for your hair loss.
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- You use other medicines on the scalp.

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**Stop use and ask a doctor if you have**

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- 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.

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**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](http://www.loeschlab.com)

NOT FOR RESALE

# EXTRA-STRENGTH FOR MEN

minoxidil solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25280-006(NDC:63981-798)
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	3 g in 60 mL

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25280-006-42	1 in 1 PACKAGE	07/30/2014	
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	ANDA075598	07/30/2014	

**Labeler** - Loesch Laboratory Consultant, INC. (026619510)

## Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	relabel(25280-006)

