

**HAIR LABS MENS EXTRA STRENGTH 5 MINOXIDIL- minoxidil liquid
HAIR RESTORATION LABS, LLC**

Hair Labs Men's Extra Strength 5% Minoxidil Solution

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 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. 5% minoxidil topical solution 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 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.

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 5% minoxidil topical solution for men. ● In clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution. ● Store at controlled room temperature 20° to 25° C (68° to 77°F).

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

1-800-784-0386 Visit Website at www.buyhairlabs.com.

Package Labeling:

| | |
|--|---|
| 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 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. 5% minoxidil topical solution 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 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. | |
| 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. | |
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| Inactive ingredients Alcohol, Propylene Glycol, Purified Water | |
| Questions or comments? 1-800-784-0386 Visit Website at www.buyhairlabs.com . | |

Hair Labs™
Men's
EXTRA STRENGTH
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

This Package Contains



One 60 mL (2 fl oz) Bottle of Men's Hair Labs Extra Strength (one-month supply)
One Child-Resistant Dropper Applicator
Information Leaflet with complete directions on how to use and obtain best results
(Read enclosed leaflet before use)

Made in USA
Distributed By:
Hair Restore Labs, LLC
540 S. Main St. Suite 122
Akron, OH 44311

Add Label part #
Rev. Date

NDC XXXXX-XXX-XX



Men's
EXTRA STRENGTH

5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

Reactivates Hair Follicles to Stimulate Regrowth
Clinically Proven to Help Regrow Hair
Topical Solution
Unscented

Not for Use by Women

One Month Supply
60mL (2 fl oz)

Hair Labs™
Men's
EXTRA STRENGTH
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

5% Minoxidil Topical Solution, USP 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. 5% Minoxidil Topical Solution, USP has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



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

For Best Results:
Apply Directly to Scalp.
Use Twice Daily.



LOT#

EXP:

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Men's
Hair Labs™
EXTRA STRENGTH
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

Unscented

Clinically Proven to Help Regrow Hair

Reactivates Hair Follicles to Stimulate Regrowth

Topical Solution

One Month Supply
60mL (2 fl oz)

Read and keep carton and leaflet for full product information.

Active Ingredient Minoxidil 5% w/v

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. • 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

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

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

- **Apply one mL 2 times a day** directly onto the scalp in the hair loss area
- **See carton and enclosed leaflet for complete directions**
- Using more or more often will not improve result
- Continued use is necessary, or hair loss will begin again.

Other Information
Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

Inactive Ingredients Alcohol, Propylene Glycol, Purified Water

Questions? Call toll-free phone number 1(800)784-0386 or reach us online at www.buyhairlabs.com.

For Best Results: Apply Directly to Scalp Twice Daily.

Made in USA
Distributed By:
Hair Restore Labs, LLC,
540 S. Main St. Suite 122
Akron, OH 44311

Label part#
Rev. date

HAIR LABS MENS EXTRA STRENGTH 5 MINOXIDIL

minoxidil liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83454-404 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1) | MINOXIDIL | 50 mg in 1 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:83454-404-00 | 1 in 1 BOX | 05/15/2023 | |
| 1 | | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076239 | 05/15/2023 | |

Labeler - HAIR RESTORATION LABS, LLC (089765024)

Revised: 5/2023

HAIR RESTORATION LABS, LLC