

**MINOXIDIL EXTRA STRENGTH FOR MEN- minoxidil solution**  
**Roman Health Ventures Inc.**

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**Minoxidil Topical Solution for Men**

***Drug Facts***

1 Bottle Carton

***Active ingredient***

Minoxidil, USP 5% w/v

3 Bottle Carton

***Active ingredient***

Minoxidil 5% w/v

1 Bottle Carton

***Purpose***

Hair regrowth treatment for men

3 Bottle Carton

***Purpose***

Hair regrowth treatment

1 Bottle Carton

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

3 Bottle Carton

***Use*** to regrow hair on the scalp

***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 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 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.

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

**Inactive ingredients** Alcohol, propylene glycol, purified water

**Questions? 1-424-347-6299 between 9:30 am and 9:00 pm EST, Monday-Friday.**

Distributed by

Roman Health Ventures, Inc.

116 W. 23rd Street, 4th Floor

New York, NY 10011

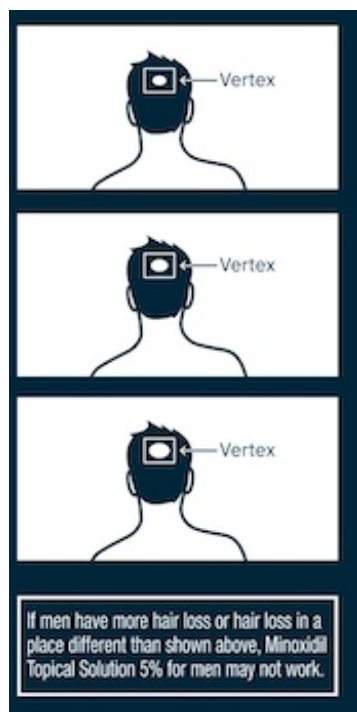
getroman.com

**NOT FOR USE BY WOMEN:**

May grow facial hair. May be harmful if used during pregnancy or breast-feeding.

**For best results, apply directly to scalp twice daily.**

**Minoxidil Topical Solution USP 5%** is for men who have a general thinning of the 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% for men has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



**Single Bottle Package**

NDC 72484-095-03  
Men's Extra Strength

**HAIR REGROWTH TREATMENT**

**roman MINOXIDIL TOPICAL SOLUTION USP 5%**

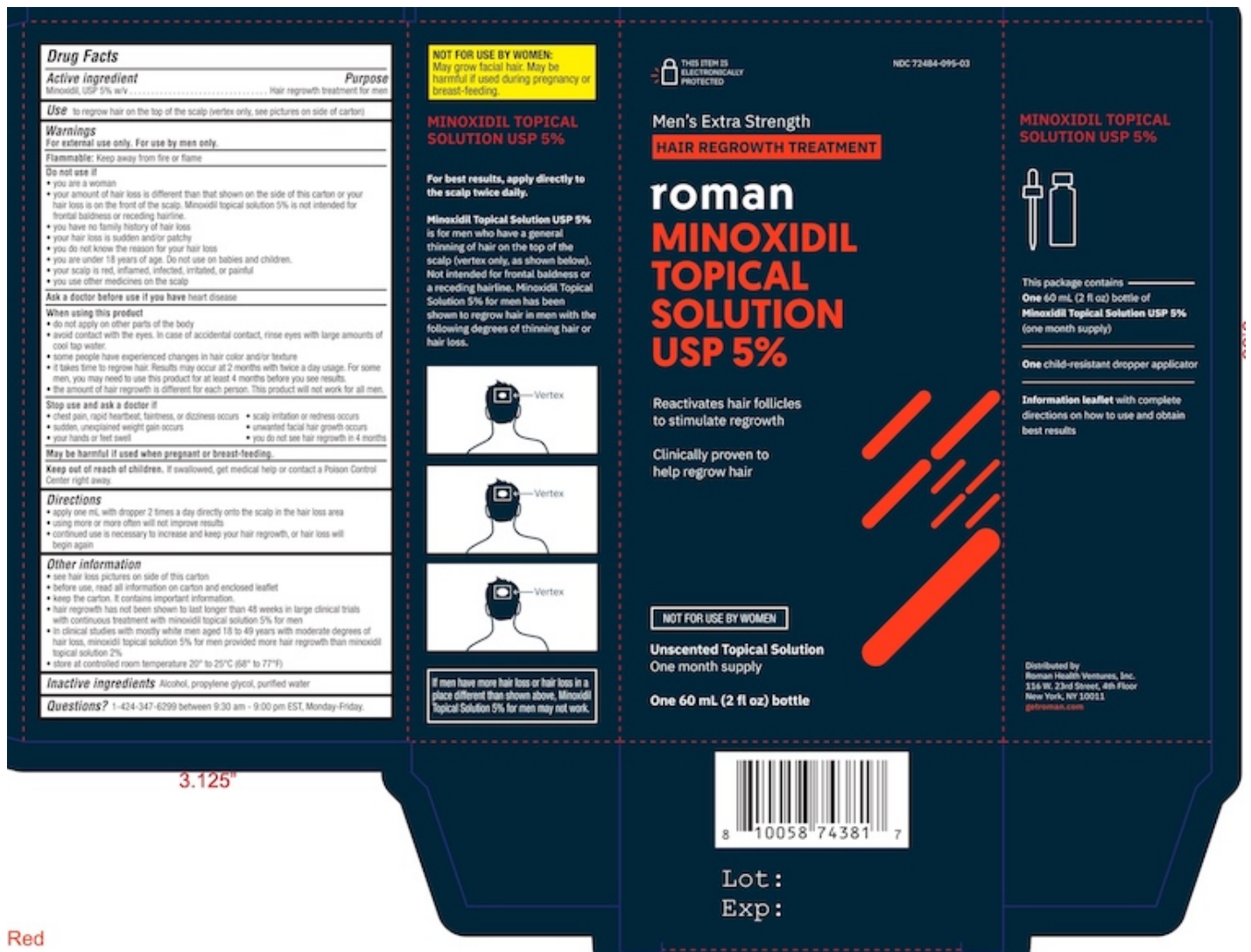
Reactivates hair follicles to stimulate regrowth  
Clinically proven to help regrow hair

NOT FOR USE BY WOMEN

**Unscented Topical Solution**

One month supply

**One 60 mL (2 fl oz) Bottle**



Red

## Three bottle package

NDC 72484-095-06

Men's Extra Strength

## HAIR REGROWTH TREATMENT

roman

## MINOXIDIL TOPICAL SOLUTION USP 5%

Reactivates hair follicles to stimulate regrowth

Clinically proven to help regrow hair

NOT FOR USE BY WOMEN

Unscented Topical Solution

Three month supply

Three 60 mL (2 fl oz) bottles

**Drug Facts**

|  |   |
|--|---|
| <b>Active ingredient</b><br>Minoxidil 5% w/v | <b>Purpose</b><br>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**

- 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, itchy 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 use and ask a doctor if**

- chest pain, rapid heartbeat, dizziness, 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 1 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°)

**Inactive ingredients** alcohol, propylene glycol, purified water


**Questions?**  
1-844-347-6299 between 9:30 am - 9:00 pm ET, Monday-Friday

**NOT FOR USE BY WOMEN:**  
May grow facial hair. May be harmful if used during pregnancy or breast-feeding.

**MINOXIDIL TOPICAL SOLUTION USP 5%**

**For best results, apply directly to the scalp twice daily.**

**Minoxidil Topical Solution USP 5%** is for men who have a general thinning of hair on the top of the scalp (verruca only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil Topical Solution 5% for men has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



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

NDC 72484-095-06

**Men's Extra Strength  
HAIR REGROWTH TREATMENT**


**roman  
MINOXIDIL  
TOPICAL  
SOLUTION  
USP 5%**

Reactivates hair follicles to stimulate regrowth  
Clinically proven to help regrow hair

**NOT FOR USE BY WOMEN**

**Unscented Topical Solution**  
Three month supply

**Three 60 mL (2 fl oz) bottles**




**MINOXIDIL TOPICAL SOLUTION USP 5%**

This package contains  
**Three 60 mL (2 fl oz) bottles of Minoxidil Topical Solution USP 5% (three month supply)**

One child-resistant dropper applicator

Information leaflet with complete directions on how to use and obtain best results

Distributed by  
Roman Health Ventures, Inc.  
156 W. 23rd Street, 8th Floor  
New York, NY 10011  
rhm.com



8 10058 74382 4

Lot:  
Exp:

## MINOXIDIL EXTRA STRENGTH FOR MEN

minoxidil solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72484-095 |
| <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         | 5 g in 100 mL |

### Inactive Ingredients

| Ingredient Name                            | Strength |
|--|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M)          |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) |          |
| <b>WATER</b> (UNII: 059QF0KO0R)            |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:72484-095-03 | 1 in 1 CARTON       | 05/08/2020           |                    |

|   |                  |   |            |  |
|---|------------------|---|------------|--|
| 1 |                  | 60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |            |  |
| 2 | NDC:72484-095-06 | 3 in 1 CARTON   | 05/19/2021 |  |
| 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               | ANDA076239                               | 05/08/2020           |                    |

**Labeler** - Roman Health Ventures Inc. (081317350)

Revised: 6/2023

Roman Health Ventures Inc.