

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

Minoxidil Spray

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 scalp (vertex only, see picture on side of carton)

3 Bottle Carton

Use to regrow hair on 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

Directions

Prime the sprayer by holding the bottle the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist

Apply one mL with spray (6 sprays) 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

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

Keep the carton. It contains important information.

In clinical studies of mostly white men aged 18-45 years with moderate degrees of hairloss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution

Store at controlled room temperature 20 to 25C (68 to 77F)

Inactive ingredients Alcohol, propylene glycol, purified water

Questions? 1-424-347-6299 Visit website at ro.co

Distributed by

Roman Health Ventures, Inc.

116 W. 23rd Street, 4th Floor

New York, NY 10011

www.ro.co

NOT FOR USE BY WOMEN:

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

Minoxidil 5% Topical Solution, USP

Minoxidil 5% Topical Solution

is for men who have a general

thinning of hair on the top of

the scalp vertex only, as

shown below. Not intended

for frontabl baldness or a

receding hairline. Minoxidil

Topical Solution 5% has been

shown to regrow hair in men

with the following degrees of

thinning hair or hairloss.

If men have more hair loss or hair loss in

a place different than showing above, Minoxidil

Topical Solution 5% for men may not work.

For best results:

Apply directly to scalp. Use twice daily.

Three Bottle Package

NDC xxxxx-xxx-xx

roman

HAIR

REGROWTH

TREATMENT

5% Minoxidil Topical Solution, USP

Extra Strength formula for men

Clinically proven to help regrow hair

Reactivates hair follicles to stimulate growth

Easy precision sprayer

Unscented topical solution

Three month supply

3- 60 mL (2 fl oz) bottles

Total 180 mL (6 fl oz)

Not for use by women



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50000MV

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

5% Minoxidil Topical Solution, USP

5% Minoxidil Topical Solution 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 following degrees of thinning hair of hair loss.



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

For best results:
Apply directly to scalp.
Use twice daily.



Drug Facts

Active ingredient Minoxidil 5% w/v **Purpose** Hair regrowth treatment for men

Use To regrow hair on 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, 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

- Prime the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist.
- Apply one mL with spray (6 sprays) 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.
- 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.
- Keep the carton. It contains important information.
- In clinical studies of mostly white men aged 18-45 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? 1-424-347-6299 Visit website at roco

Lot:
Exp:

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NDC XXXXX - XXX - XX

roman HAIR REGROWTH TREATMENT

5% Minoxidil Topical Solution, USP

- Extra strength formula for men
- Clinically proven to help regrow hair
- Reactivates hair follicles to stimulate regrowth

Easy
precision
sprayer



Unscented topical solution

Three month supply
3 - 60 mL (2 fl oz) bottles
Total 180 mL (6 fl oz)

Not for use by women

5% Minoxidil Topical Solution, USP



This package contains

Three 60 mL (2 fl oz) bottles of Minoxidil Topical Solution (three-month supply).

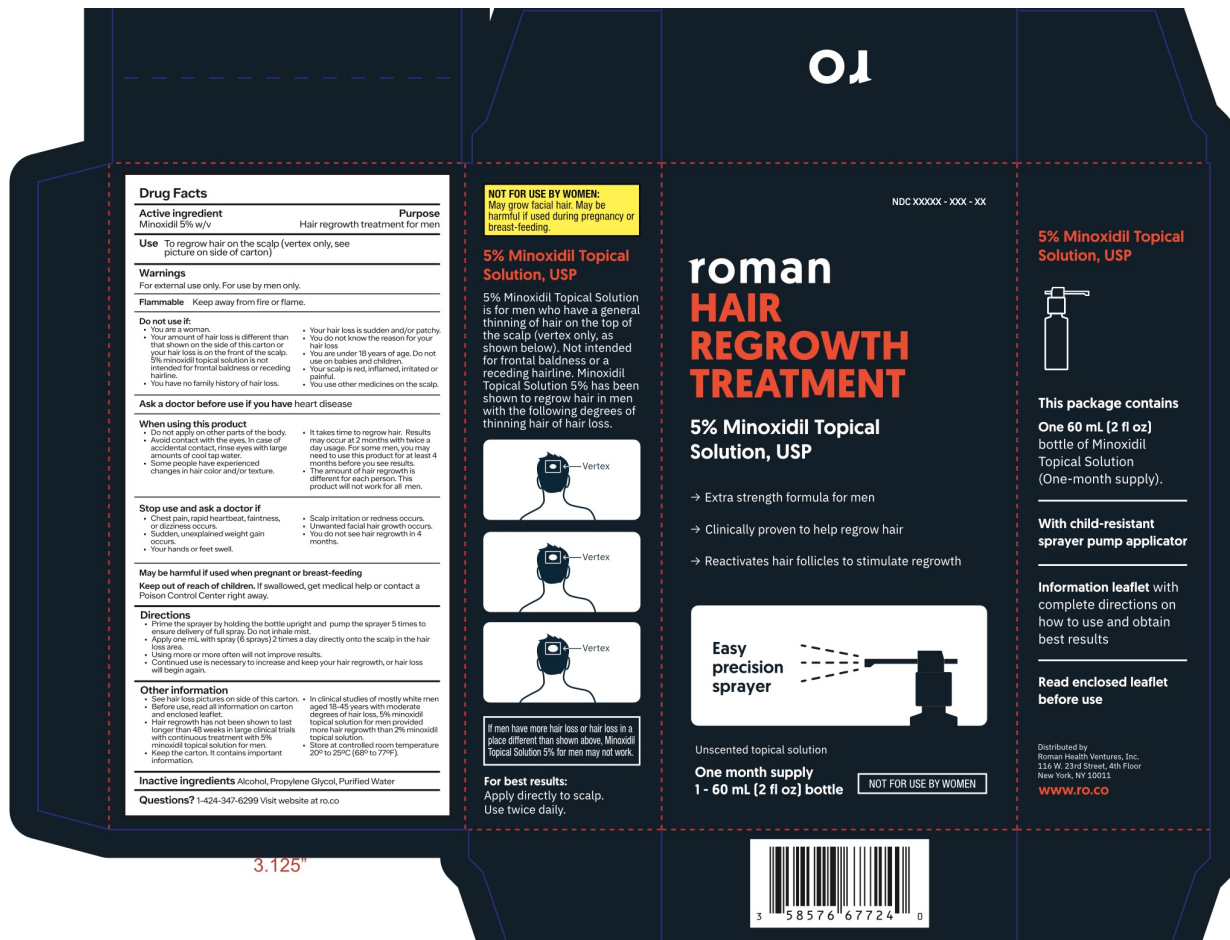
With child-resistant sprayer pump applicator

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

Read enclosed leaflet before use

Distributed by
Roman Health Ventures, Inc.
116 W. 23rd Street, 4th Floor
New York, NY 10011
www.roco

Single Bottle Package



NDC XXXXX-XXX-XX

roman

Hair Regrowth Treatment

5% Minoxidil Topical Solution, USP

Extra Strength formula for men

Clinically proven to help regrow hair

Reactivates hair follicles to stimulate regrowth

Easy precision sprayer

Unscented topical solution

One month supply

1 - 60 mL (2 fl oz) bottle

Not for use by women.

MINOXIDIL EXTRA STRENGTH FOR MEN

minoxidil spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72484-097
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72484-097-01	3 in 1 CARTON	01/01/2024	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:72484-097-02	1 in 1 CARTON	01/01/2024	
2		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	01/01/2024	

Labeler - Roman Health Ventures Inc. (081317350)

Revised: 9/2023

Roman Health Ventures Inc.