

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 frontotopical 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

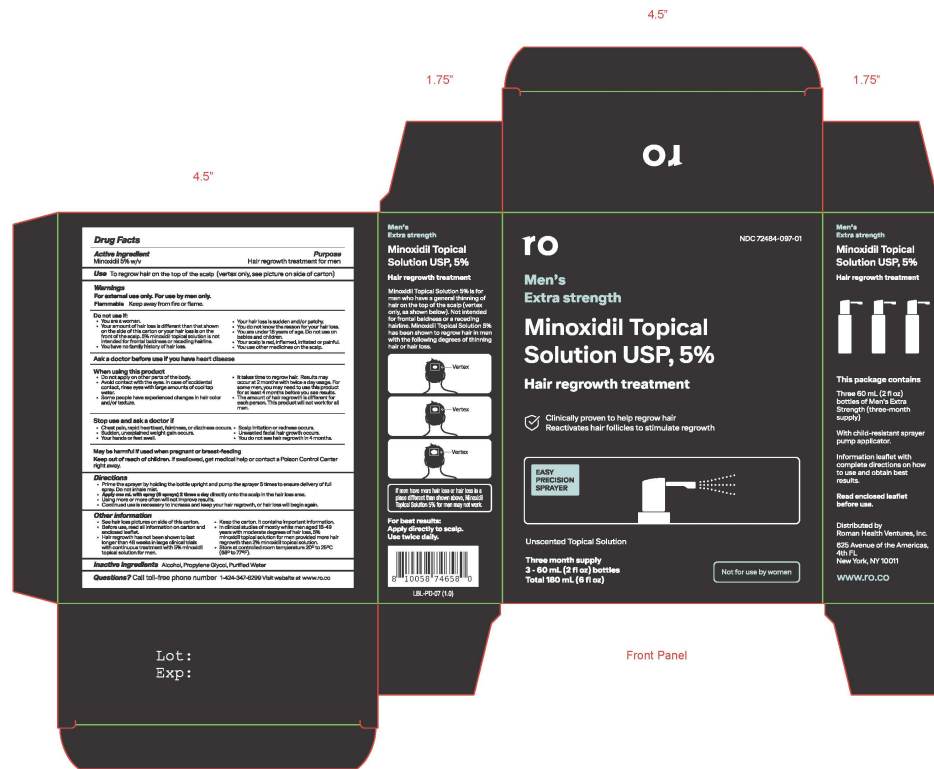
Three month supply

3- 60 mL (2 fl oz) bottles

Total 180 mL (6 fl oz)

Not for use by women

Ro Minoxidil Spray_3mo
Updated 02.25.25



Single Bottle Package

NDC XXXXX-XXX-XX

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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

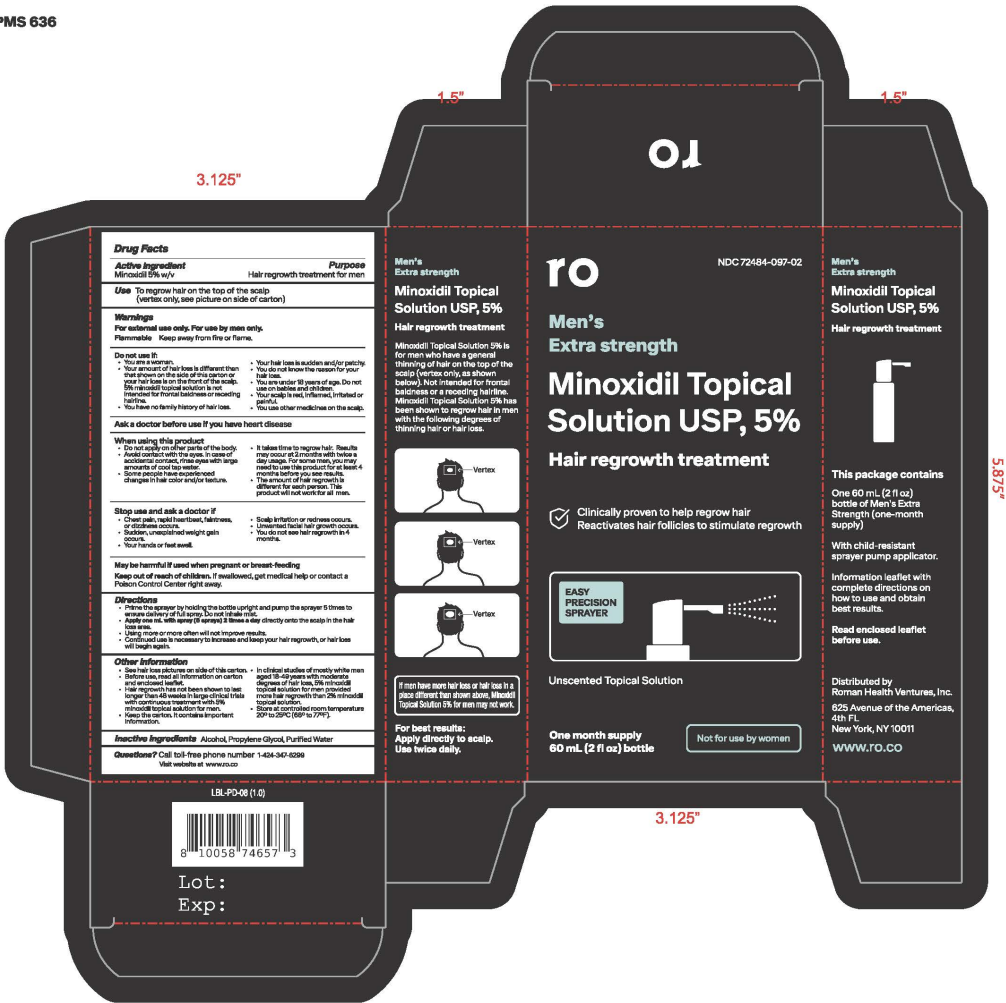
Easy precision sprayer

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: 1/2025

Roman Health Ventures Inc.