

REGROWTHX HAIR REGROWTH TREATMENT MINOXIDIL- minoxidil solution
Nimex Group Inc

RegrowthX Hair Regrowth Treatment 5% Minoxidil Topical Solution

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 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 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 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?

800-375-0182

- Visit Website at regrowthX.com

Package Labeling:

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 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 it: • 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 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 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? 800-375-0182

• Visit Website at regrowthx.com

RegrowthX

EXTRA STRENGTH
FOR MEN

5% MINOXIDIL TOPICAL
SOLUTION, USP

HAIR REGROWTH TREATMENT

This Package Contains



One 60 mL (2 fl oz) Bottle of
Men's RegrowthX Extra Strength
(one-month supply).

One child-resistant dropper
application

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

(Read enclosed leaflet before use)

Made in USA
Distributed By:
SALES MASTER GROUP INC.
1375 Coney Island Ave PMB 1005
Brooklyn, NY 11230

Label only
Rev. date

Top Dermatologist-Recommended
Ingredient

HAIR REGROWTH TREATMENT

RegrowthX

5%
MINOXIDIL TOPICAL SOLUTION, USP
EXTRA STRENGTH FOR MEN

REACTIVATES
Hair Follicles
To Stimulate Regrowth

Topical Solution

**CLINICALLY PROVEN TO HELP
REGROW HAIR**
Unscented

NOT FOR USE BY WOMEN

One Month Supply / 60mL (2 fl oz)
MADE IN USA

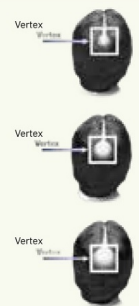
RegrowthX

EXTRA STRENGTH
FOR MEN

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 No.
Expiration
Date

Top Dermatologist
Recommended Ingredient

HAIR REGROWTH TREATMENT

MEN'S

RegrowthX

EXTRA STRENGTH

5% MINOXIDIL
TOPICAL SOLUTION, USP

Reactivates Hair Follicles
To Stimulate Regrowth

Topical Solution

CLINICALLY PROVEN TO HELP
REGROW HAIR

Unscented

NOT FOR USE BY WOMEN

One Month Supply / 60mL (2 fl oz)
MADE IN USA

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 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 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 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? 800-375-0182

• Visit Website at regrowthX.com

For Best Results:

- Apply Directly To Scalp
- Use Twice Daily

SPACE FOR LOT AND EXP.

Made in USA
Distributed by:
SALES MASTER GROUP INC,
1375 Coney Island Ave PMB 1005
Brooklyn, NY 11230

Label part#
Rev. date

REGROWTHX HAIR REGROWTH TREATMENT MINOXIDIL

minoxidil solution

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87148-881			
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: 059QF0KO0R)						
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		

1	NDC:87148-881-00	1 in 1 BOX	09/10/2025	
1		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	09/10/2025	

Labeler - Nimex Group Inc (030137642)

Registrant - Pure Source, LLC (080354456)