

**THICK HEAD EXTRA STRENGTH FOR MEN 5 MINOXIDIL TOPICAL-
minoxidil spray
PROFECTUS BEAUTY, LLC**

THICK HEAD Extra Strength for Men 5% Minoxidil Topical Solution

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment

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 • 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 18-45 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 or comments?

1-(800)-555-5163

Visit Website at www.thickhead.com

Package Labeling:



EXTRA STRENGTH FOR MEN
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

NDC# 70550-602-01



EXTRA STRENGTH FOR MEN
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment



EXTRA STRENGTH FOR MEN
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

Minoxidil Topical Solution 5% is for men who have a general thinning of hair on 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 or hair loss.

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 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, 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 • 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 18-45 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 or comments? 1-(800)-555-5163
Visit Website at www.thickhead.com

This Package Contains

- One 60 mL (2 fl.oz) Bottle of Men's Thick Head 5% Minoxidil Topical Solution, USP Hair Regrowth Treatment Extra Strength (one-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)



Made in USA
Distributed by: THICK HEAD, LLC.
Jersey City, NJ-07310

Label part# 90022-4000-01 Rev.

EXTRA STRENGTH FOR MEN
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

MEN



Not For Use by Women

- Reactivates Hair Follicles to Stimulate Regrowth
- Clinically proven to Help Regrow Hair
- Unscented

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



One Month Supply
60 mL (2 fl. oz.)

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

90022D



Lot No.
Expiration Date:

NDC# 70550-602-01



EXTRA STRENGTH FOR MEN
5% Minoxidil Topical Solution, USP
Hair Regrowth Treatment

Not For Use by Women

Reactivates Hair Follicles to Stimulate Regrowth

Clinically proven to Help Regrow Hair

Unscented

Topical Solution

One Month Supply
60 mL (2 fl. oz.)

Read and keep carton and leaflet for full product information

Active IngredientMinoxidil 5%

Warnings

For external use only. For use by men only.

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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 with sprayer (6 sprays) 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 results
- 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) 555-5163 or reach us online at website www.thickhead.com

For Best Results: Apply Directly to Scalp Twice Daily



Made in USA
Distributed by: Thick Head, LLC
111 Town Square Place, Suite 1130
Jersey City, NJ 07310

90022D

THICK HEAD EXTRA STRENGTH FOR MEN 5 MINOXIDIL TOPICAL

minoxidil spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70550-602
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:70550			

1	NDC: 70550-602-01	1 in 1 BOX	10/02/2023	
1		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		10/02/2023	

Labeler - PROPECTUS BEAUTY, LLC (118310694)

Revised: 9/2023

PROPECTUS BEAUTY, LLC