

**NAVI HAIR SOLUTIONS MENS HAIR REGROWTH TREATMENT- minoxidil
5% solution**

United Distribution of MD, LLC

Navi Hair Solutions Men's Hair Regrowth Treatment

Minoxidil 5% w/v

Hair Regrowth Treatment for Men

USE

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

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 shown on the side of this carton or 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 or children
- Your scalp is red, inflamed, infected, irritated, or painful
- You use other medicines on the scalp

Ask your 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 heart beat, faintness, or dizziness occurs
- Sudden, unexplained weight gain occurs
- Your hands or feet swell
- Scalp irritation or redness occurs
- You get unwanted facial hair growth

- You do not see hair regrowth in 4 months

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 the 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 provide more hair regrowth than 2% minoxidil topical solution
- Store at controlled room temperature 20 ° to 25 °C (68 ° to 77 °F)

Alcohol, Propylene Glycol, Purified Water

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.

Questions or comments? 1-800-924-0978 customerservice@navihair.com

Visit our website at www.navihair.com

Drug Facts

Active Ingredient 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 the side of the 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 the 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 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 solution.
*store at controlled room temperature 20° to 25°C (68° to 77°F)

Inactive ingredients Alcohol, Propylene Glycol, Purified Water

Questions or comments? 1-800-624-6678 customerservice@navihair.com
Visit our website at www.navihair.com

NDC XXXXX-XXX-XX

NAVI
HAIR SOLUTIONS

Men's
Hair Regrowth Treatment

**Extra Strength
5% Minoxidil
Topical Solution, USP**

This Package Contains:



One 60 mL (2 fl oz) Bottle of
Navi Hair Solutions Men's
Hair Regrowth Treatment Extra Strength
(One Month Supply)
With Child-resistant dropper applicator
Information leaflet with complete directions
on how to use and obtain best results.
(Read enclosed leaflet before use)

Made in USA
Distributed By:
United Distribution of MD LLC
1748 E. Joppa Road
Parkville, MD 21224

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NAVI
HAIR SOLUTIONS

Men's
Hair Regrowth Treatment

**Extra Strength
5% Minoxidil
Topical Solution, USP**
Hair Regrowth Treatment

NAVI
HAIR SOLUTIONS

Men's
Hair Regrowth Treatment

**Extra Strength
5% Minoxidil
Topical Solution, USP**

Topical
Unscented
Clinically Proven
To Help regrow hair
Reactivates hair follicles to
stimulate regrowth

Not for Use by Women

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

NAVI
HAIR SOLUTIONS

Men's
Hair Regrowth Treatment

**Extra Strength
5% Minoxidil
Topical Solution, USP**

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:

NAVI HAIR SOLUTIONS MENS HAIR REGROWTH TREATMENT

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82524-002
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82524-002-01	1 in 1 BOX	01/24/2022	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	01/24/2022	

Labeler - United Distribution of MD, LLC (030345600)

Revised: 1/2022

United Distribution of MD, LLC