

**NAVI HAIR SOLUTIONS WOMENS HAIR REGROWTH TREATMENT- minoxidil
2% solution**

United Distribution of MD, LLC

Navi Hair Solutions Women's Hair Regrowth Treatment

Minoxidil 2% w/v

Hair regrowth treatment

USE

Use to regrow hair on the top of the scalp

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

Your amount of hair loss is different than shown on the side of this carton, because this product may not work for you

You have no family history of hair loss

Your hair loss is sudden and/or patchy

Your hair loss is associated with childbirth

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 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 re-grow hair. 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 women.

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

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

In clinical studies of mostly white women aged 18-45 years with moderate degrees of hair loss, the following responses to Minoxidil Topical Solution 2% was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (19% had moderate regrowth; 40% had minimal hair regrowth). This compares with the 7% of women reporting moderate hair regrowth after using a placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

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

Alcohol, Propylene Glycol, Purified Water

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

Visit our website at www.navihair.com

NAVI
HAIR SOLUTIONS

Women's
Hair Regrowth Treatment

2% Minoxidil
Topical Solution, USP
Hair Regrowth Treatment

NAVI
HAIR SOLUTIONS
Women's
Hair Regrowth Treatment

2% Minoxidil
Topical Solution, USP

Minoxidil Topical Solution 2% is for women who have a general thinning of hair on the top of the scalp as shown. Minoxidil Topical 2% has been shown to regrow hair in women with the following degrees of thinning hair or hair loss.



If women have more hair loss than shown above, Minoxidil Topical Solution 2% may not work.



Do not use if you have patchy hair loss as shown above.
For Best Results:
Apply Directly to Scalp.
Use Twice Daily.

NDC XXXXX-XXX-XX

NAVI
HAIR SOLUTIONS
Women's
Hair Regrowth Treatment

2% Minoxidil
Topical Solution, USP

This Package Contains:



One 60 mL (2 fl oz) Bottle of
Navi Hair Solutions

Women's Hair Regrowth Treatment

(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
1746 E. Joppa Road
Parkville, MD 21234

Label Part #NHSWM
Rev. Date 12/21

NAVI
HAIR SOLUTIONS

Women's
Hair Regrowth Treatment

2% Minoxidil
Topical Solution, USP

Topical
Unscented
Clinically Proven
To Help regrow hair

Reactivates hair follicles to
stimulate regrowth

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

Drug Facts
Active Ingredient Purpose
Minoxidil 2% w/v.....Hair Regrowth Treatment

Use to regrow hair on the scalp

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Do not use if: *your amount of hair loss is different than that shown on the side of this carton, because this product may not work for you *you have no family history of hair loss *your hair loss is sudden and/or patchy *your hair loss is associated with childbirth *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. 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 women.

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 areas *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 *in clinical studies of mostly white women aged 18 - 45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 6 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate regrowth after using placebo, the liquid without minoxidil in it, for 6 months (7% had moderate regrowth; 33% had minimal regrowth).
*store at controlled room temperature 20° to 25°C (68° to 77°F)

Inactive Ingredients: Alcohol, Propylene Glycol, Purified Water

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Lot No.

Expiration Date:

NAVI HAIR SOLUTIONS WOMENS HAIR REGROWTH TREATMENT

minoxidil 2% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82524-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82524-001-01	1 in 1 BOX	01/21/2022	
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	ANDA078176	01/21/2022	

Labeler - United Distribution of MD, LLC (030345600)

Revised: 1/2022

United Distribution of MD, LLC