

**DANIEL ALAIN HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil
2% solution
Daniel Alain, Inc**

Daniel Alain - Women's 2% Minoxidil Topical Solution

Minoxidil 2% w/v

Hair regrowth treatment

USE

to regrow hair on scalp

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 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 your 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 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. You may need to use this product 2 times a day for at least 4 months before you see results.
- The amount of hair regrow 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.

If swallowed, get medical help, or contact a Poison Control Center right away.

DIRECTIONS

- Apply 1 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

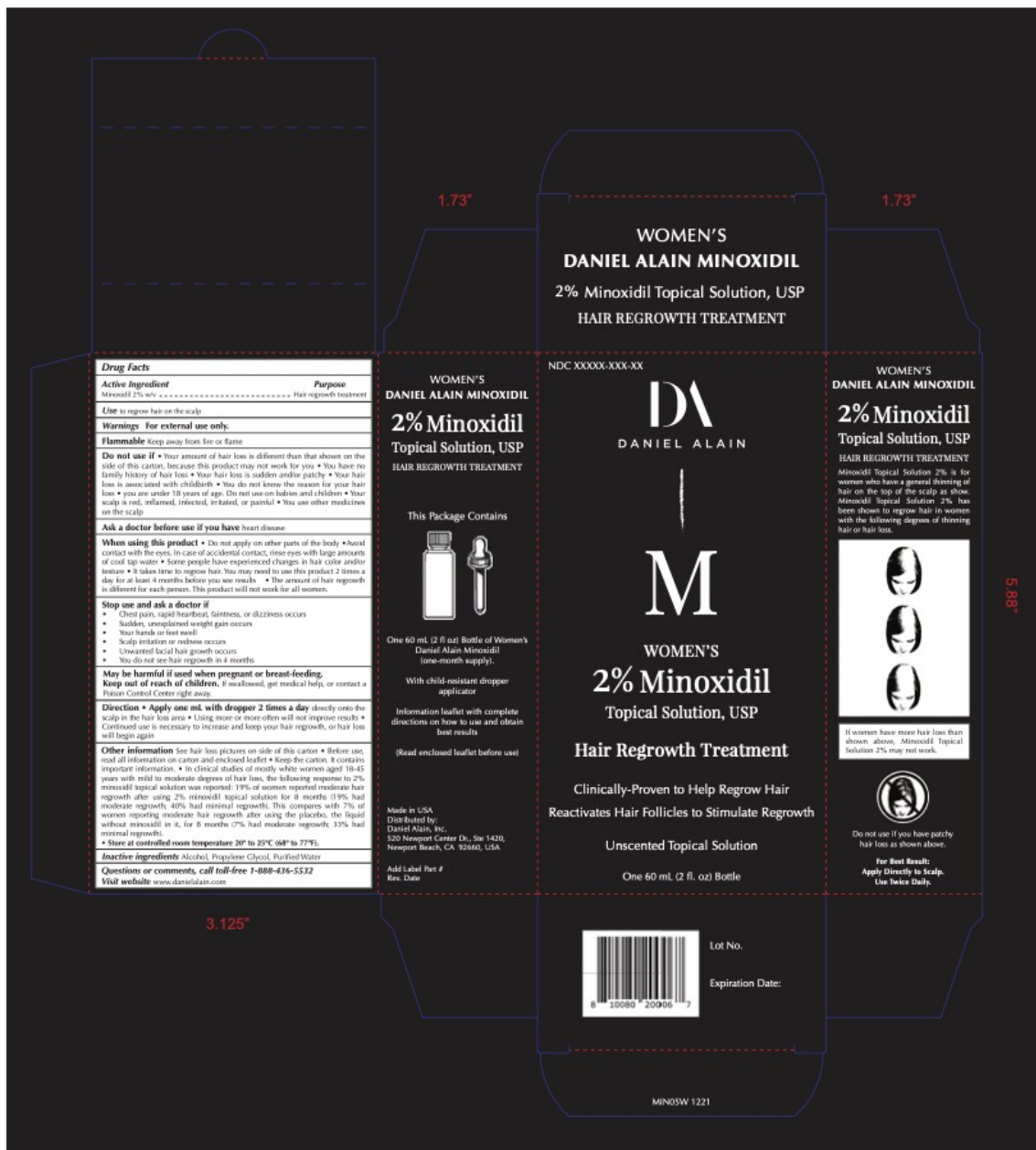
OTHER INFORMATION

- 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.
- 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 solutions was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth: 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth: 33% had minimal regrowth).
- Store at controlled room temperature 68 ° - 77 °F (20 ° - 25 °C).

Alcohol, Propylene Glycol, Purified Water

Questions or comments, call toll-free 1-888-436-5532

Visit website www.danielalain.com



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minoxidil 2% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82545-001
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: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82545-001-01	1 in 1 BOX	02/04/2022	
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	02/04/2022	

Labeler - Daniel Alain, Inc (010990313)

Revised: 2/2022

Daniel Alain, Inc