

DANIEL ALAIN EXTRA STRENGTH HAIR REGROWTH TREATMENT FOR MEN- minoxidil 5% solution

Daniel Alain, Inc

Daniel Alain Men's Extra Strength 5% Minoxidil Topical Solution

Minoxidil 5% w/v

Hair regrowth treatment for men

USE

to regrow hair on the top of the scalp (vertex only, see picture on side on 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 that shown on the side of this carton or your hair loss is on the front of the scalp. 5% 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 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 change 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.

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 68° to 77°F (20° to 25°C).

Alcohol, Propylene Glycol, Purified Water

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

Visit website: www.danielalain.com



DANIEL ALAIN EXTRA STRENGTH HAIR REGROWTH TREATMENT FOR MEN

minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82545-002
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	
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82545-002-01	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		ANDA076239	02/04/2022	

Labeler - Daniel Alain, Inc (010990313)

Revised: 2/2022

Daniel Alain, Inc