

AZELOMAX FORTE- minoxidil 5% solution/ drops
TRILOGIC LTD

AZELOMAX FORTE 5% MINOXIDIL TOPICAL SOLUTION, USP

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 pictures on side of 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 o to 25 oC (68 o to 77 oF)

Alcohol, Propylene Glycol, Purified Water

Questions or comments? +7-499-753-024-34

- Visit Website at www.simone.su

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

May be harmful if used when pregnant or breast-feeding.



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 • 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 45 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 degree 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? • +7-499-753-024-34
• Visit Website at www.azeloma.com

This Package Contains:



- One 60 mL (2 fl oz) Bottle of Men's Product Name Extra Strength (one month supply).



- One 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: OOO
TRILOGIC LTD.
Krizhanovskogo st.14/3
117218 MOSCOW-RUSSIA

**AZELOMAX
FORTE**

**EXTRA STRENGTH
5% MINOXIDIL TOPICAL
SOLUTION, USP
HAIR REGROWTH TREATMENT**

**Reactivates Hair Follicles
To Stimulate Regrowth
Clinically Proven To Help Regrow Hair
Topical Solution
Unscented**

Not For Use By Women

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

Minoxidil Topical Solution 5% 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. Minoxidil Topical Solution 5% has been shown to regrow hair in men with the following degrees of thinning hair of 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

Label Part#
Rev. Date

NDC XXXXX-XXX-XX

**AZELOMAX
FORTE**
EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

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

**Topical Solution
Unscented**

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

Read and keep carton and leaflet for full product information

Active Ingredient: Minoxidil 5% w/v

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 • 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 2 times a day directly onto the scalp in the hair loss area • see enclosed leaflet for complete Directions for Use
• using more or more often will not improve results • continued use is necessary or hair loss will begin again

Inactive Ingredients
Alcohol, Propylene Glycol, Purified Water

Questions? Call (800) TRILOGIC LTD.
+7 (499) 753-04-34) or reach us on the internet at www.simone.ru

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

Label Par#

Rev. Date

Made in USA
Distributed By: 000 TRILOGIC LTD.
Kizhbanovskogo st.14/3 117218
MOSCOW-RUSSIA

AZELOMAX FORTE

minoxidil 5% solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73237-002
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)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73237-002-01	1 in 1 BOX	07/10/2019	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	07/10/2019	

Labeler - TRILOGIC LTD (682372062)

Revised: 1/2023

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