

AXELOFEIN- minoxidil 2% solution/ drops
TRILOGIC, LTD

AZELOFEIN HAIR GROWTH SOLUTION
2% MINOXIDIL TOPICAL SOLUTION

Minoxidil 2% w/v

USE

Use to regrow hair on the scalp

Hair regrowth treatment

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree 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 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 everyone.

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

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.

- 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
- In clinical studies of mostly white women aged 18-45 years with moderate degrees of hair loss, the following responses to 2% minoxidil topical solution 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 o to 25 oC (68 o to 77 oF)

Alcohol, Propylene Glycol, Purified Water

Questions or comments? +7-499-753-04-34

- Visit Website at www.simone.su

Alcohol, Propylene Glycol, Purified Water



• 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
- 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 regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if

- chest pain, rapid heartbeat, dizziness, 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 • combing hair 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 8 months (19% had moderate regrowth, 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth, 33% had minimal regrowth).
- store at USP controlled room temperature 20° to 25°C (68° to 77°)

Inactive ingredients: Alcohol, Propylene Glycol, Purified Water

Questions or comments? • 7-499-753-04-34
• Visit Website at www.azefen.com

THIS PACKAGE CONTAINS:



- One 60 mL (2 fl oz) Bottle of AZELOFEN (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

**2% MINOXIDIL
TOPICAL SOLUTION**
HAIR REGROWTH TREATMENT

**Revitalizes Hair Follicles
To Stimulate Regrowth**
Clinically Proven To Help Regrow Hair

**Topical Solution
Unscented**

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

AZELOFEN is for women who have a general thinning of hair on the top of the scalp as shown. AZELOFEN 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, AZELOFEN may not may not work.



Do not use if you have patchy hair loss as shown above.



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Lot No.

Expiration

Label Part#

Rev. Date

<p>NDC#</p> <p>AZELOFEIN</p> <p>2% Minoxidil Topical Solution Hair Regrowth Treatment</p> <p>UNSCENTED</p> <p>CLINICALLY PROVEN TO HELP GROW HAIR</p> <p>REVITALIZES HAIR FOLLICLES</p> <p>TOPICAL SOLUTION</p> <p>One Month Supply 60 mL (2 fl oz)</p>	<p>Read and keep carton and leaflet for full product information</p> <p>Active ingredient Minoxidil 2% w/v</p> <p>Warnings For external use only. Flammable. Keep away from fire or flame. Do not use if</p> <ul style="list-style-type: none"> • 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 <p>Ask a doctor before use if you have heart disease</p> <p>When using this product</p> <ul style="list-style-type: none"> • 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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 	<p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • apply one mL 2 times a day directly onto the scalp in the hair loss area • see inner carton and enclosed leaflet for complete directions • using more or more often will not improve results • continued use is necessary or hair loss will begin again <p>Inactive ingredients alcohol, propylene glycol, purified water</p> <p>Questions? Call (OOO TRILOGIC LTD. +7 (499) 753-04-34) or reach us on the internet at www.simone.su</p> <p>Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)</p> <p>LOT# Label part# EXP Rev. date</p> <p>Dist by: TRILOGIC LTD Address: Krzizhanovskogo street 14 str. 3, 117218, MOSCOW, RUSSIA</p>
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minoxidil 2% solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73237-001
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:73237-001-01	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	ANDA078176	07/10/2019	

Labeler - TRILOGIC, LTD (682372062)

Revised: 1/2023

TRILOGIC, LTD