ZOTOS PROFESSIONAL NUTRI FOR WOMEN 2% MINOXIDIL TOPICAL SOLUTION- minoxidil solution HENKEL US OPERATIONS CORPORATION

ZOTOS PROFESSIONAL Nutri for Women 2% Minoxidil Topical Solution

Drug Facts

Active ingredient

Minoxidil 2% w/v

Purpose

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 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 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

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 the 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)

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

Questions?

Call toll-free 1-800-242-9283 Visit Website at zotosprofessional.com

Package Labeling:

for women

XO·IJ2NU

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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 all women.

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

Inactive ingredients Alcohol, Propylene Glycol, Purified Water

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<u>ZOTOS</u> nutriox for women

THIS PACKAGE CONTAINS

One 2 fl oz / 60 ml ottle of Nutri-Ox for wor



dropper applicator

LY SOURCED INGREDIENTS/COMPONENTS

800-242-9283

zotosprofes

ZOTOS

nutriox for women

2% minoxidil topical solution,

reactivates hair follicles

to stimulate regrowth

clinically proven to

one month supply

2 fl oz / 60 mL

help regrow hair

SULOR nutri-ox for women 2% minoxidil

topical solution, usp

hair regrowth treatment

reactivates hair follicles to stimulate regrowth

clinically proven to help regrow hair

one month supply 2Floz / 60 mL

<u>ZOTOS</u> nutriox for women

2% minoxidil topical solution. usp

hair regrowth treatment

Minoxidil Topical Solution 2% Minoxidil Topical Solution 2% is for women who have a general thinning of hair on the top of the scalp as shown. Minoxidil Topical Solution 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

FOR BEST RESULTS:



NDC XXXXX-XXX-XX SOLOZ **1Utri·ox**® for women

2% minoxidil topical solution, usp

hair regrowth treatment

reactivates hair follicles to stimulate regrowth

clinically proven to help regrow hair

topical solution - unscented

one month supply 2 fl oz / 60 mL

Read & keep carton and leaflet for full product information

Active ingredient

Minoxidil 2% w/v

Warnings

For external use only

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 your hair loss is sudden and/or patchy
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- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children
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- some people have experienced changes in hair color and/or texture

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Directions

- apply one mL with dropper 2 times a day directly
- onto the scalp in the hair loss area
 see carton and enclosed leaflet for complete directions
- 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

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

Inactive ingredients Alcohol, Propylene Glycol, Purified Water

Questions? Call toll-free 1-800-242-9283 Visit Website at zotosprofessional.com

For Best Results:

Apply Directly to Scalp Twice Daily

FOR U.S.: @2023 DISTRIBUTED BY: HENKEL CORPORATION, DARIEN, CT 06820. MADE IN THE USA OF GLOBALLY SOURCED INGREDIENTS/COMPONENTS.

2917746 **REV DATE**

ZOTOS PROFESSIONAL NUTRI FOR WOMEN 2% MINOXIDIL TOPICAL SOLUTION

minoxidil solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50663-395

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1) MINOXIDIL 20 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R)

Packaging

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:50663- 395-00	1 in 1 BOX	03/06/2023	
l	1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing I	larketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA078176	03/06/2023			

Labeler - HENKEL US OPERATIONS CORPORATION (966706145)

Revised: 2/2023 HENKEL US OPERATIONS CORPORATION