WOMENS ROGAINE UNSCENTED- minoxidil solution Johnson & Johnson Consumer Inc.

WOMEN'S Rogaine ® UNSCENTED

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 degree 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 everyone.

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 booklet
- 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 800-764-2463 or 215-273-8755 (collect)
- visit www.rogaine.com

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

#1 DERMATOLOGIST

RECOMMENDED BRAND

WOMEN'S

Rogaine ®

2% Minoxidil

Topical Solution

Hair Regrowth

Treatment

REACTIVATES

HAIR FOLLICLES

TO STIMULATE

REGROWTH

CLINICALLY PROVEN

TO HELP REGROW HAIR

Topical Solution

UNSCENTED

One Month Supply

One 60 mL (2 fl oz) Bottle



WOMENS ROGAINE UNSCENTED

minoxidil solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0090

Route of Administration TOPICAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
l	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)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69968- 0090-1	1 in 1 CARTON	08/01/2010		
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:69968- 0090-3	3 in 1 CARTON	08/01/2010		
2		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019501	08/01/2010	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 4/2023 Johnson & Johnson Consumer Inc.