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- FDA PI

# Rogaine Women's: Package Insert / Prescribing Info

Package insert / product label

Generic name: minoxidil

Dosage form: aerosol, foam

Drug class: Miscellaneous topical agents

Medically reviewed by Drugs.com. Last updated on Nov 18, 2024.

### On This Page

Indications and Usage

Warnings

Dosage and Administration

Storage and Handling

**Drug Facts** 

## **Active ingredient**

Minoxidil 5% w/w (without propellant)

## **Purpose**

Hair regrowth treatment for women

## Indications and Usage for Rogaine Women's

to regrow hair on the top of the scalp (see pictures on side of this carton)

## **Warnings**

For external use only.

## **Extremely Flammable**

Avoid fire, flame, or smoking during and immediately following application.

### Do not use if

• your degree of hair loss is different than that shown on 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 use more than directed
- 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 3 months with **once daily** use. For some women, you may need to use this product **once a day** for at least 6 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 6 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.

## Rogaine Women's Dosage and Administration

- see enclosed booklet for complete directions on how to use
- apply half a capful once daily directly to the scalp in the hair loss area
- · massage into scalp with fingers, then wash hands well
- · 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

## Storage and Handling

- · 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.
- store at controlled room temperature 20° to 25° C (68° to 77° F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

## **Inactive ingredients**

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

### **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

## PRINCIPAL DISPLAY PANEL - 60 g Can Carton

#1 DERMATOLOGIST RECOMMENDED BRAND

WOMEN'S

Rogaine ®

5% Minoxidil

**Topical Aerosol** 

Hair Regrowth

Treatment

REACTIVATES
HAIR FOLLICLES
TO STIMULATE
REGROWTH

CLINICALLY PROVEN
TO REGROW HAIR

Once-a-Day

### **UNSCENTED**

## TWO MONTH SUPPLY ONE 60 g (2.11 OZ) CAN



#### **Drug Facts**

#### Active ingredient

**Purpose** 

Minoxidil 5% w/w (without propellant) ... Hair regrowth treatment for women

Use to regrow hair on the top of the scalp (see pictures on side of this carton)

For external u Extremely Fla ial use only. Flammable: Avoid fire, flame, or smoking during and immediately following application.

#### Do not use if

- your degree of hair loss is different than that shown on side of this carton because this product may not work for you you have no family history of hair loss
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- 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.
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- you use other medicines on the scalp

#### Ask a doctor before use if you have heart disease

#### When using this product

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  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 3 months with once-daily use. For some women, you may need to use this product once a day for at least 6 months before you see results.
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- you do not see hair regrowth in 6 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

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   massage into scalp with fingers, then wash hands well
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### Other information

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#### **Ouestions?**

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

#### **DIRECTIONS FOR USE**

See information booklet with complete directions on how to use and obtain best results.



#### 1: PREP HANDS WITH COLD WATER

Rinse your fingers in **cold** water and dry them. **Note**: foam will melt on contact with warm surfaces.



## 2: OPEN CHILD RESISTANT

Be sure to align arrow on the cap with arrow on blue ring. Tilt cap back and pull off.



#### 3: DISPENSE VERTICALLY ONTO A COLD SURFACE

Hold the can straight upside down. If you hold the can at an angle, foam may not dispense properly. Press nozzle to dispense half a capful of foam onto cold surface (e.g. dish, or cold hands).



#### 4: APPLY TO SCALP, NOT HAIR

Part your hair to expose hair loss area. Massage foam into scalp, not hair. Repeat until all hair loss areas have been covered.



#### 5: CLOSE CAP AND **WASH HANDS**

Snap cap back into place. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.

WOMEN'S ROGAINE® Foam is for women who have a general thinning of hair on the top of the scalp (as shown below) and has been sho









If women have more hair loss than shown ab WOMEN'S ROGAINE® Foam may not work.

THIS PACKAGE CONTAINS:
One 60 g (2.11 oz) can of WOMEN'S ROGAINE®
Foam (two month supply)

is subject to trademark protection. The overal look and design of this packaging



36623002

Stiefel Laboratories. technology licensed from Product incorporates U.S. Patent No. 6,946,120 ● 1&JCI 2019

> Active Made in Italy Skillman, NJ 08558



#### **WOMENS ROGAINE UNSCENTED**

minoxidil aerosol, foam

**Product Information** 

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69968-0030

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

**MINOXIDIL** (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1) MINOXIDIL 50 mg in 1 g

**Inactive Ingredients** 

Ingredient Name Strength

**BUTANE (UNII: 6LV4FOR43R)** 

**BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K)

CETYL ALCOHOL (UNII: 936JST6JCN)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

GLYCERIN (UNII: PDC6A3C0OX)

ISOBUTANE (UNII: BXR49TP611)

LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)

POLYSORBATE 60 (UNII: CAL22UVI4M)

PROPANE (UNII: T75W9911L6)

WATER (UNII: 059QF0KO0R)

ALCOHOL (UNII: 3K9958V90M)

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0030-1	1 in 1 CARTON	04/01/2011	
1		60 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:69968-0030-2	2 in 1 CARTON	04/01/2011	
2		60 g in 1 CAN; Type 0: Not a Combination Product		
3	NDC:69968-0030-3	3 in 1 CARTON	04/01/2011	
3		60 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

NDA NDA021812 04/01/2011

Labeler - Kenvue Brands LLC (118772437)

## Frequently asked questions

· Does minoxidil work for beards?

## More about Rogaine Women's (minoxidil topical)

- · Check interactions
- Compare alternatives
- Reviews (6)
- · Side effects
- Dosage information
- During pregnancy
- Drug class: miscellaneous topical agents
- Breastfeeding

### **Patient resources**

· Women's Rogaine advanced reading

### **Professional resources**

• Minoxidil (Topical) monograph

### Other brands

Hair Regrowth Treatment for Women, Hair Regrowth Treatment for Men

### Other formulations

- Rogaine
- Rogaine For Men Extra Strength

## Related treatment guides

Alopecia

Medical Disclaimer

#### **DRUG STATUS**

### **Availability**

or Rx and/or OTC

**Pregnancy & Lactation** 

ം Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

□ Drug history at FDA

### **User Reviews & Ratings**

6 Reviews

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