

REGOXIDINE (FOR WOMEN)- minoxidil aerosol, foam
Innovus Pharmaceuticals, Inc.

Regoxidine®
5% (For Women)

Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for women

Use

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 (1-800-222-1222).

Directions

- see enclosed leaflet 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

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.
- 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

butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

- Call **1-866-923-4914**

Distributed by:
Innovus Pharmaceuticals, Inc.
Englewood, CO 80112

PRINCIPAL DISPLAY PANEL - Two 60 g Can Package

NDC 57483-540-31

Circle™

Regoxidine®

Minoxidil Topical
Aerosol, 5%
(For Women)

Hair Regrowth
Treatment

ONCE-A-DAY
FOAM
for Women

Unscented

Reactivates Hair Follicles to
Stimulate Regrowth

Clinically Proven to Regrow Hair

#1 Dermatologist Recommended Active Ingredient†

*Compare to the active ingredient of Women's Rogaine®

FOUR MONTH SUPPLY
TWO 2.11 OZ (60 g) CANS

NDC 57483-540-31



Regoxidine[®]

Minoxidil Topical Aerosol, 5% (For Women)

Hair Regrowth Treatment



Reactivates Hair Follicles to
Stimulate Regrowth

DIRECTIONS FOR USE

See information leaflet 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 CAP
Be sure to align arrow on the cap with arrow on white 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 a **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.

Stimulate Regrowth Clinically Proven to Regrow Hair

#1 Dermatologist Recommended Active Ingredient*
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FOUR MONTH SUPPLY
TWO 2.11 OZ (60 g) CANS



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.

Read and keep package and leaflet for full product information.



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- 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

Minoxidil Topical Aerosol, 5% (For Women) is for women who have a general thinning of hair on the top of the scalp (as shown below) and 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**

- 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

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- 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.
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- 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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Questions?

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Aerosol, 5% (For Women) may not work.

THIS PACKAGE CONTAINS:

Two 2.11 oz (60 g) cans of **Minoxidil Topical Aerosol, 5% (For Women)** (four month supply)

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Women's Rogaine.®

Made in Israel

Distributed by:
Innovus Pharmaceuticals, Inc.
Englewood, CO 80112
www.crclehealth.com

†In the U.S.
Source: AlphaImpactRx



REGOXIDINE (FOR WOMEN)

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-540
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
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cetyl alcohol (UNII: 936JST6JCN)	
anhydrous citric acid (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
isobutane (UNII: BXR49TP611)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
BUTANE (UNII: 6LV4FOR43R)	
polysorbate 60 (UNII: CAL22UVI4M)	
propane (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE (white to off-white foam)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-540-31	2 in 1 PACKAGE	11/12/2019	
1		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
ANDA	ANDA209074	04/22/2019	

Revised: 12/2022

Innovus Pharmaceuticals, Inc.