

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

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**Regoxidine®**  
**5% (For Men)**

***Drug Facts***

**Active ingredient**

Minoxidil 5% w/w (without propellant)

**Purpose**

Hair regrowth treatment for men

**Use**

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

**Warnings**

**For external use only.**

**For use by men only.**

**Extremely Flammable:** Avoid fire, flame, or smoking during and immediately following application.

**Do not use if**

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical foam is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- 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. 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 all men.

**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 (1-800-222-1222).

**Directions**

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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**

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- 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 - Three 60 g Can Package**

NDC 57483-530-31

C•rcle™

Regoxidine®

Minoxidil Topical  
Aerosol, 5% (For Men)

Hair Regrowth  
Treatment

EASY-TO-USE  
FOAM

Unscented

Reactivates Hair Follicles to Stimulate Regrowth  
Clinically Proven to Help Regrow Hair

#1 Dermatologist Recommended Active Ingredient†  
\*Compare to the active ingredient of Men's Rogaine®

Not For Use by Women

THREE MONTH SUPPLY  
THREE 2.11 OZ (60 g) CANS

NDC 57483-530-31



# Regoxidine<sup>®</sup>

## Minoxidil Topical Aerosol, 5% (For Men)

Hair Regrowth  
Treatment



Reactivates Hair Follicles to Stimulate Regrowth  
Clinically Proven to Help Regrow Hair

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THREE MONTH SUPPLY  
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### THIS PACKAGE CONTAINS

- Three 2.11 oz (60 g) cans of Minoxidil Topical Aerosol, 5% (For Men) (three month supply)

### 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.



#### 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.



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## Drug Facts

### Active ingredient

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### Purpose

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### Warnings

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#### Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp.
- 5% minoxidil topical foam is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- 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**

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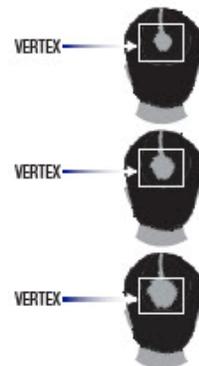
### Inactive ingredients

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

**Minoxidil Topical Aerosol, 5% (For Men)** is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. **Minoxidil Topical Aerosol, 5% (For Men)** has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.



If men have more hair loss or hair loss in a place different than shown above, **Minoxidil Topical Aerosol, 5% (For Men)** may not work.



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

Made in Israel

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

<sup>†</sup>In the U.S.  
Source: AlphaspectRx

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**REGOXIDINE (FOR MEN)**

minoxidil aerosol, foam

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57483-530
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Minoxidil</b> (UNII: 5965120SH1) (Minoxidil - UNII:5965120SH1)	Minoxidil	50 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>isobutane</b> (UNII: BXR49TP611)	
<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
<b>BUTANE</b> (UNII: 6LV4FOR43R)	
<b>polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>propane</b> (UNII: T75W9911L6)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>stearyl alcohol</b> (UNII: 2KR89I4H1Y)	

**Product Characteristics**

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-530-31	3 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	01/02/2019	

**Labeler** - Innovus Pharmaceuticals, Inc. (962507187)

Revised: 12/2022

Innovus Pharmaceuticals, Inc.