

REGOXIDINE (FOR WOMEN) - minoxidil aerosol, foam
INNOVUS PHARMACEUTICALS, INC.

Drug Facts

Active ingredient

Minoxidil USP 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 (1-800-222-1222) right away.

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** 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
- 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

Alcohol, anhydrous citric acid, butane, butylated hydroxy toluene, cetyl alcohol, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

Call toll-free **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Visit our website at www.crclehealth.com

Distributed By:

Innovus Pharmaceuticals, Inc.
5740 Kietzke Lane #300
Reno, Nevada 89511

www.crclehealth.com

Made in India

Code: TS/DRUGS/58039/2020

IMPORTANT INFORMATION ABOUT

Minoxidil Topical Aerosol 5% (For Women)

Hair Regrowth Treatment

REACTIVATES HAIR FOLLICLES TO STIMULATE REGROWTH

CLINICALLY PROVEN TO REGROW HAIR

Once-a-Day

Foam For Women

UNSCENTED

Minoxidil Topical Aerosol 5% (For Women)

Hair Regrowth Treatment

Save this leaflet for future reference.

Please read this leaflet carefully. It will help you understand how to use Women's Minoxidil Topical Aerosol 5% (Foam) and what to expect from its use. It takes time to regrow hair. Results may occur at 3 months with **once daily** usage. For some women, you may need to use this product for at least 6 months before you see results. If you have any questions after reading this leaflet, or anytime while using Women's Minoxidil Topical Aerosol 5% (Foam), you should ask your health care professional or call us at

toll-free **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST).

WHAT IS WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Women's Minoxidil Topical Aerosol 5% (Foam) is a white foam containing 5% minoxidil for use only on the scalp to help regrow hair in women.

WHO MAY USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Women's Minoxidil Topical Aerosol 5% (Foam) may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Minoxidil Topical Aerosol 5% (Foam) is for general thinning of hair on the top of the scalp as shown below. Women's Minoxidil Topical Aerosol 5% (Foam) has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Women's Minoxidil Topical Aerosol 5% (Foam) may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, see your doctor.**



WHO SHOULD NOT USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Women's Minoxidil Topical Aerosol 5% (Foam) will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Women's Minoxidil Topical Aerosol 5% (Foam) will not improve hair loss due to:

- Damage from the use of hair care products which cause scarring or deep burns of the scalp.
- Hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp.

Do not use if you are not sure of the reason for your hair loss.

WILL WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) WORK FOR ME?

The amount of hair regrowth is different for each person. Not everyone will respond to Women's Minoxidil Topical Aerosol 5% (Foam). The response to Women's Minoxidil Topical Aerosol 5% (Foam) cannot be predicted. No one will be able to grow back all their hair.

To see your best results with Women's Minoxidil Topical Aerosol 5% (Foam), make sure you apply the product directly to the scalp **once daily**. For some Women's Minoxidil Topical Aerosol 5% (Foam) may not work.

HOW SOON CAN I EXPECT RESULTS FROM USING WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Women's Minoxidil Topical Aerosol 5% (Foam) also takes time. Generally, new hair growth is slow for a Women's Minoxidil Topical Aerosol 5% (Foam) user. Results may be seen as early as 3 months with **once daily** use. For some women, it may take at least 6 months for results to be seen. If you do not see any results after 6 months, stop using Women's Minoxidil Topical Aerosol 5% (Foam) and seek the advice of your doctor.

When you first begin to use Women's Minoxidil Topical Aerosol 5% (Foam), your hair loss may continue for up to 2 weeks. This increase in hair loss is expected and is temporary. However, if it continues after two weeks, see your physician.

IF WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) IS WORKING, WHAT WILL THE HAIR LOOK LIKE?

At first, hair growth may be soft, downy, and colorless hairs. After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

HOW LONG DO I NEED TO USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

If you respond to Women's Minoxidil Topical Aerosol 5% (Foam), you need to use it **once daily** to keep and continue the hair regrowth. Up to 3 months of usage may be needed to see your best results from Women's Minoxidil Topical Aerosol 5% (Foam).

WHAT HAPPENS IF I COMPLETELY STOP USING WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)? WILL I KEEP THE NEW HAIR?

Continuous use of Women's Minoxidil Topical Aerosol 5% (Foam) is needed to maintain hair regrowth. If you stop using Women's Minoxidil Topical Aerosol 5% (Foam), the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

HOW DO I USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

For best results, apply half a capful **once a day** directly to the scalp in the hair loss area. Using more than the recommended amount will not improve results. Each can should last two months, if used as directed. Never take this product by mouth or apply to other parts of the body. Please refer to the "Directions for Use" section of this leaflet.

WHEN DO I USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Apply Women's Minoxidil Topical Aerosol 5% (Foam) **once daily**. If you apply at night, allow application to dry completely before going to bed.

WHAT IF I FORGET TO USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) OR MISS A DOSE?

If you miss one daily doses of Women's Minoxidil Topical Aerosol 5% (Foam), just continue with your next dose. You should not make up for missed doses.

CAN I USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) MORE THAN ONCE A DAY? WILL IT WORK FASTER, BETTER?

No. Women's Minoxidil Topical Aerosol 5% (Foam) will not work faster or better if used more than **once a day**. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

WHAT KIND OF SHAMPOO SHOULD I USE WITH WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

If you wash your scalp before applying Women's Minoxidil Topical Aerosol 5% (Foam), use a mild shampoo.

CAN I USE HAIR SPRAYS, MOUSSES, CONDITIONERS, GELS, ETC.?

Yes. There is no reason to change your usual hair care routine when using Women's Minoxidil Topical Aerosol 5% (Foam). However, you should apply Women's Minoxidil Topical Aerosol 5% (Foam) first and wait for it to dry before applying your styling aids.

CAN I HAVE MY HAIR COLORED OR PERMED OR USE HAIR RELAXERS WHILE USING WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Yes. We have no evidence that coloring or perming, or using relaxers on your hair change the effect of Women's Minoxidil Topical Aerosol 5% (Foam). However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we recommend the following precautions:

1. To avoid possible scalp irritation, you should make sure all of the Women's Minoxidil Topical Aerosol 5% (Foam) has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply Women's Minoxidil Topical Aerosol 5% (Foam) on the same day that you use a chemical treatment on your hair.
3. Do not use Women's Minoxidil Topical Aerosol 5% (Foam) for 24 hours after using any chemicals to make sure your scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue use of Women's Minoxidil Topical Aerosol 5% (Foam) as usual.
4. Simply restart your normal Women's Minoxidil Topical Aerosol 5% (Foam) routine. There is no need to use more Women's Minoxidil Topical Aerosol 5% (Foam) to make up for missed applications.

Missing one day of Women's Minoxidil Topical Aerosol 5% (Foam) will not affect your hair regrowth results.

CAN I APPLY WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) AND WASH MY HAIR AN HOUR LATER?

No. For Women's Minoxidil Topical Aerosol 5% (Foam) to work best, you should allow Women's Minoxidil Topical Aerosol 5% (Foam) to remain on the scalp for about 4 hours before washing.

DIRECTIONS FOR USE:

- Please familiarize yourself with the instructions below in order to help make your product application a success.
- This product should be used **ONCE DAILY**, EVERY DAY.
- To be effective, it is important to apply the product **DIRECTLY TO YOUR SCALP** and **NOT TO YOUR HAIR** so that it can easily get to your hair follicles to help regrow your hair.
- There is no need to shampoo your hair before using the product. If you wish to shampoo your hair before applying Women's Minoxidil Topical Aerosol 5% (Foam), towel dry your hair so that the skin on the scalp is dry.

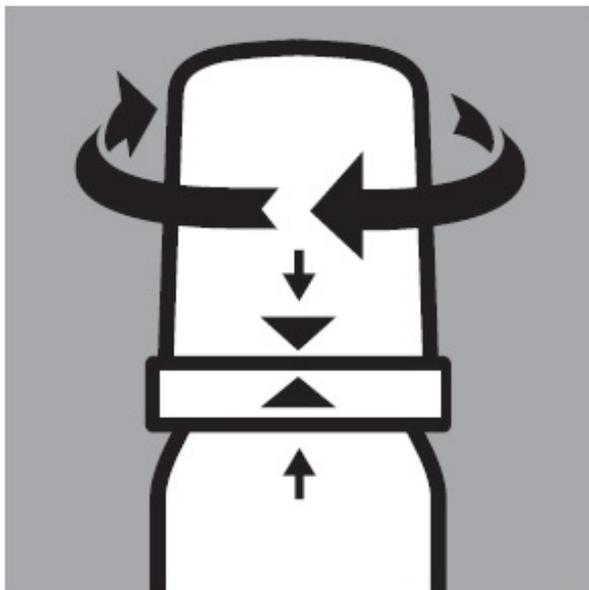
1: PREP HANDS WITH COLD WATER

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.



ARE THERE ANY SPECIAL WARNINGS ABOUT THE USE OF WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

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 more than that shown on the other side of this leaflet, 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 your 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 experience changes in hair color and/or texture
- it takes time to regrow hair. Results may occur in 3 months with **once daily** use. For some women you may need to use this product **once daily** 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 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 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 (1-800-222-1222) right away.

WHAT ARE THE MOST COMMON SIDE EFFECTS WITH WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

The most common side effects are itching and other skin irritation of the treated area of the scalp. Women's Minoxidil Topical Aerosol 5% (Foam) contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Women's Minoxidil Topical Aerosol 5% (Foam) accidentally gets into these areas, rinse with large amounts of cool tap water. Stop using Women's Minoxidil Topical Aerosol 5% (Foam) and contact your doctor if irritation persists.

CAN WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) PRODUCE UNWANTED HAIR?

Unwanted hair growth has been reported on the face and on other parts of the body with Women's Minoxidil Topical Aerosol 5% (Foam) use. The unwanted hair growth may be caused by the transfer of Women's Minoxidil Topical Aerosol 5% (Foam) to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Women's Minoxidil Topical Aerosol 5% (Foam).

If you experience unwanted hair, discontinue using Women's Minoxidil Topical Aerosol 5% (Foam) and see your doctor for recommendations about appropriate treatment. After stopping use of Women's Minoxidil Topical Aerosol 5% (Foam), the unwanted hair, if caused by the use of Women's Minoxidil Topical Aerosol 5% (Foam), should go away over time. You can take steps to decrease the chances for unwanted hair growth:

1. Limit the application of Women's Minoxidil Topical Aerosol 5% (Foam) only to the scalp;
2. If you use your hands to apply Women's Minoxidil Topical Aerosol 5% (Foam), wash your hands thoroughly afterwards, and
3. Allow sufficient drying time before going to bed (usually 2 to 4 hours before going to bed after applying Women's Minoxidil Topical Aerosol 5% (Foam).

CAN I USE WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM) FOR BALDNESS OR HAIR LOSS IN BABIES OR CHILDREN?

No. Women's Minoxidil Topical Aerosol 5% (Foam) must not be used to treat baldness or hair loss in babies and children.

WHAT FACTORS MAY INCREASE THE RISK OF SERIOUS SIDE EFFECTS WITH WOMEN'S MINOXIDIL TOPICAL AEROSOL 5% (FOAM)?

Women's Minoxidil Topical Aerosol 5% (Foam) should be applied only to the scalp. The risk of side effects may be greater when Women's Minoxidil Topical Aerosol 5% (Foam) is applied to other parts of the body.

If you have any other questions, ask your health care professional or call us toll-free **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST).

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Save this leaflet for future reference.

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Questions? Call toll-free **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Revised: 06/2025

PRINCIPAL DISPLAY PANEL - One 60 g Can Label

NDC 57483-175-01

C•rcle™

Minoxidil Topical

Aerosol 5%

(For Women)

Regoxidine®

Hair Regrowth

Treatment

ONCE-A-DAY

FOAM

for Women

Unscented

Reactivates Hair Follicles
to Stimulate Regrowth

Clinically Proven to

Regrow Hair

**TWO MONTH SUPPLY
ONE 2.11 OZ (60 g) Can**

FOR 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
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.

Read and keep package and leaflet for full product information

Inactive ingredients

Alcohol, anhydrous citric acid, butane, butylated hydroxy toluene, cetyl alcohol, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Questions? Call toll-free 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

NDC 57483-175-01



**Minoxidil Topical
Aerosol 5%
(For Women)
Regoxidine®**

**Hair Regrowth
Treatment**



**Reactivates Hair Follicles
to Stimulate Regrowth**

**Clinically Proven to
Regrow Hair**

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

Active ingredient

Minoxidil USP 5% w/w (without propellant)

Warnings

For external use only.

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

Do not use if

- 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
- your hair loss is associated with childbirth

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

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

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 (1-800-222-1222) right away.

**Distributed By: Innovus Pharmaceuticals, Inc.
5740 Kietzke Lane #300, Reno, Nevada 89511
www.crclehealth.com**

Made in India

Code: TS/DRUGS/58039/2020

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08.25

P 1437119

Unvarnished Zone
(dotted line not for printing)
12 x 36 mm

White Opaque Area

**This area also
White Opaque**

*Lot: XXXXXXXXX
Exp.: YYYY-MMM
Prefix, Variables of Lot and Exp
shall be printed online during packing.

PRINCIPAL DISPLAY PANEL - Two 60 g Can Package

NDC 57483-175-12

C'rcle™

**Minoxidil Topical
Aerosol 5%
(For Women)**

Regoxidine®

Hair Regrowth Treatment

**ONCE-A-DAY
FOAM
for Women**

Unscented

Reactivates Hair Follicles
to Stimulate Regrowth

Clinically Proven
to Regrow Hair

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

**FOUR MONTH SUPPLY
TWO 2.11 OZ (60 g) CANS**

NDC 57483-175-12

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

Drug Facts	
Active ingredient	Purpose
Minoxidil USP 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)	
Warnings	
For external use only.	
Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.	
Do not use if	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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 (1-800-222-1222) right away.	
Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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 20°C to 25°C (68°F to 77°F) (See USP Controlled Room Temperature). • 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	
Alcohol, anhydrous citric acid, butane, butylated hydroxy toluene, cetyl alcohol, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol	
Questions?	
Call toll-free 1-866-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST) Visit our website at www.circlehealth.com	

THIS PACKAGE CONTAINS:
Two 2.11 oz (60 g) cans of MINOXIDIL TOPICAL AEROSOL, 5% (For Women) (four month supply)

*This product is not manufactured or distributed by Johnson & Johnson consumer Inc. distributor of Women's Rogaine®.

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 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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3 57483 00121 6



Minoxidil Topical Aerosol 5% (For Women) Regoxidine®

Hair Regrowth Treatment



Reactivates Hair Follicles to Stimulate Regrowth
Clinically Proven to Regrow Hair

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

FOUR MONTH SUPPLY
TWO 2.11 OZ (60 g) CANS

P1060737

Unwashed Zone (dotted line not for printing) 70 x 27 mm

REGOXIDINE (FOR WOMEN)

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTANE (UNII: 6LV4FOR43R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-175-12	2 in 1 CARTON	05/03/2025	
1	NDC:57483-175-01	60 g in 1 CAN; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:57483-175-11	1 in 1 CARTON	11/14/2025	
2	NDC:57483-175-01	60 g in 1 CAN; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218616	05/03/2025	

Labeler - INNOVUS PHARMACEUTICALS, INC. (962507187)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		878100017	ANALYSIS(57483-175) , MANUFACTURE(57483-175)