

REGOXIDINE- minoxidil solution
Innovus Pharmaceuticals Inc.

REGOXIDINE (FOR WOMEN)

Active ingredient

Minoxidil 2% w/v

Purpose

Hair regrowth treatment

Use

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

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 hairloss 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 ue 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 women, 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 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 4 months

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

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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 leaflet
- 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 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 or comments?

Call **+1 800-996-5122** Monday to Friday at 8am to 5pm EST.

Visit our website at www.innovuspharma.com

Consumer Information

WOMEN'S REGOXIDINE

2% Minoxidil Topical Solution, USP

HAIR REGROWTH TREATMENT

Unscented

Save this leaflet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. REGOXIDINE contains the only ingredient that is medically proven effective to help regrow hair in women.

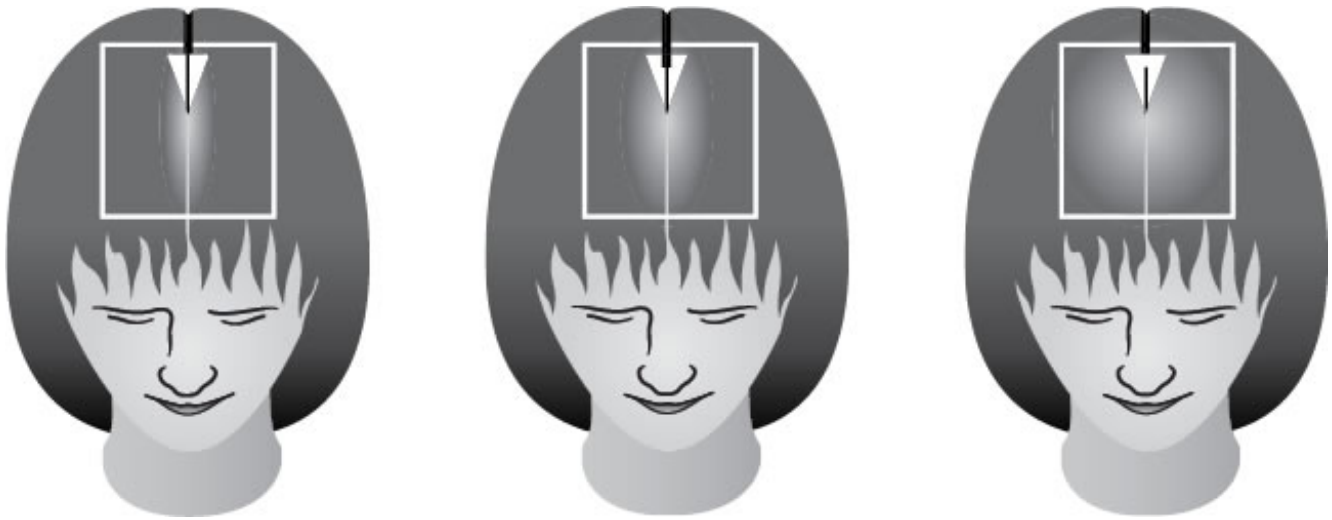
Please read this leaflet carefully. It will help you understand how to use REGOXIDINE and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using REGOXIDINE, you should ask your health care professional or call us at **+1 800-966-5122**, you can also visit our website at www.innovuspharma.com.

What is WOMEN'S REGOXIDINE?

REGOXIDINE is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

Who may use WOMEN'S REGOXIDINE?

REGOXIDINE 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 head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss. REGOXIDINE is for general thinning of hair on the top of the scalp as shown in the illustration below. REGOXIDINE has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, REGOXIDINE 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, talk to your doctor.**



Who should NOT use WOMEN'S REGOXIDINE?

REGOXIDINE 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, REGOXIDINE 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 REGOXIDINE if hair loss is patchy as shown below.

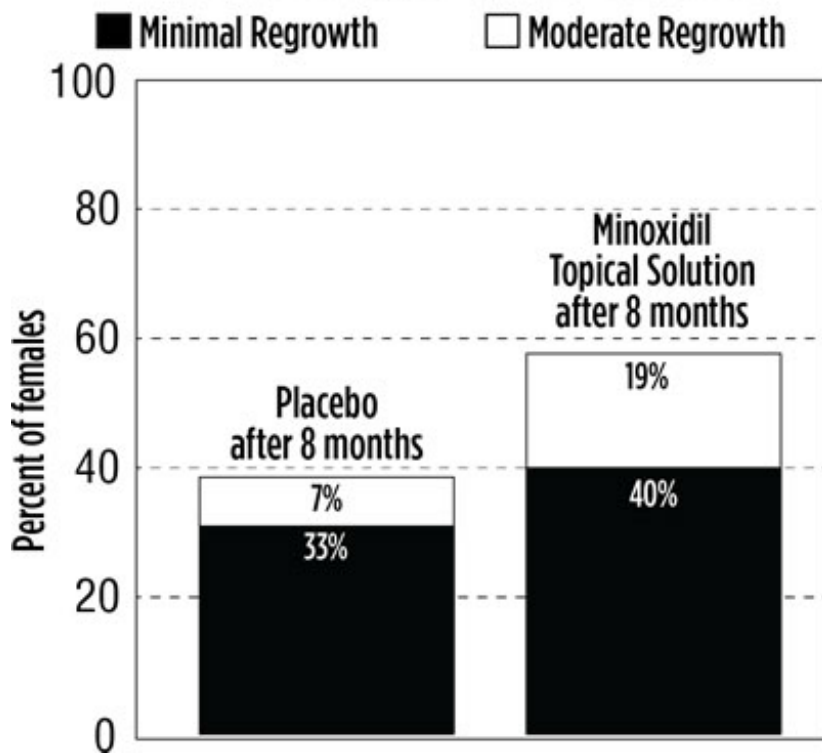


You should ask your doctor if you are unsure of the cause of your hair loss.

Will WOMEN'S REGOXIDINE work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to REGOXIDINE. The response to REGOXIDINE cannot be predicted. No one will be able to grow back all their hair. In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Minoxidil topical solution 2% was reported:

Female Response to Minoxidil Topical Solution 2% Percent reporting hair regrowth



19% of women reported moderate hair regrowth after using Minoxidil topical solution 2% for 8 months (19% had moderate regrowth. 40% had minimal regrowth). This compared with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth. 33% had minimal regrowth).

What Minimal, Moderate and Dense Hair Regrowth Will Mean For You?

	Number of Hairs	Hair Density
Minimal	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of the head.
Moderate	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as close together as hairs on the rest of the head.
Dense	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of the head.

Can WOMEN'S REGOXIDINE be used to prevent hair loss?

We do not know if REGOXIDINE will prevent hair loss.

How soon can I expect results from using WOMEN'S REGOXIDINE?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with REGOXIDINE also takes time. Generally new hair growth is slow for a REGOXIDINE user.

Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth. If you do not see hair regrowth in 4 months, stop using REGOXIDINE and see your doctor. When you first begin to use REGOXIDINE, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

If WOMEN'S REGOXIDINE is working, what will the hair look like?

At first, hair growth may be soft, downy, 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 REGOXIDINE?

If you respond to REGOXIDINE, you will need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from REGOXIDINE.

What happens if I completely stop using WOMEN'S REGOXIDINE? Will I keep the new hair?

Continuous use of REGOXIDINE is needed to maintain hair regrowth. If you stop using REGOXIDINE, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

What is the dosage of WOMEN'S REGOXIDINE?

You should apply a dose (1 mL) of REGOXIDINE directly onto the scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please refer to the "Directions for Use" section of this leaflet.

What if I miss a dose or forget to use WOMEN'S REGOXIDINE?

If you miss one or two daily doses of REGOXIDINE, just continue with your next dose. You should not make up for missed doses.

Can I use WOMEN'S REGOXIDINE more than two times a day? Will it work faster, better?

No. REGOXIDINE will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of REGOXIDINE needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

What are the most common side effects with WOMEN'S REGOXIDINE?

The most common side effects are itching and other skin irritations of the treated area of the scalp. REGOXIDINE contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If REGOXIDINE accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

What kind of shampoo should I use with WOMEN'S REGOXIDINE?

If you wash your scalp before applying REGOXIDINE, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.?

Yes. There is no need to change your usual hair care routine when using REGOXIDINE. However, you should apply REGOXIDINE 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 REGOXIDINE?

Yes. We have no information that these treatments change the effect of REGOXIDINE.

However, to avoid possible scalp irritation, you should make sure all of the REGOXIDINE has been washed off the hair and scalp before using these chemicals.

Can I apply WOMEN'S REGOXIDINE and wash my hair an hour later?

No. For REGOXIDINE to work best, you should allow REGOXIDINE to remain on the scalp for about 4 hours before washing.

Can I go swimming or out in the rain?

Yes. Avoid washing off the REGOXIDINE. If possible, apply REGOXIDINE to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying REGOXIDINE.

Can WOMEN'S REGOXIDINE produce unwanted hair?

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of REGOXIDINE 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 REGOXIDINE.

If you experience unwanted hair, discontinue using REGOXIDINE and see your doctor for recommendations about appropriate treatment. After stopping use of REGOXIDINE, the unwanted hair, if caused by the use of REGOXIDINE, should go away over time.

You can take steps to decrease the chances for unwanted hair growth:

1. limit the application of REGOXIDINE only to the scalp,
2. if you use your hands to apply REGOXIDINE, wash your hands thoroughly afterwards, and
3. allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of REGOXIDINE.

Can I use WOMEN'S REGOXIDINE for baldness or hair loss in babies and children?

No. REGOXIDINE must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of WOMEN'S REGOXIDINE?
For external use only**

Flammable: Keep away from fire or flame

Do not use if

your degree of hair loss is more than that shown on the illustration on page 1 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 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
- scalp irritation or redness occurs
- sudden, unexplained weight gain occurs
- unwanted facial hair growth occurs
- your hands or feet swell
- 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.

What other factors may increase the risk of serious side effects with WOMEN'S REGOXIDINE?

REGOXIDINE should be applied only to the scalp. The risk of side effects may be greater when it is applied to other parts of the body.

Directions for Use

1. Remove the cap. To remove, push down and turn in direction of the arrows on the cap.

2. Part your hair in the area of hair thinning/loss.

Follow the instructions below for using the dropper applicator and **apply one mL 2 times a day** directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying REGOXIDINE.

Using the Dropper Applicator

1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.



If you have any other questions, ask your health care professional or call us at **+1 800-996-5122**. You can also visit our website at www.innovuspharma.com

Store at USP Controlled Room Temperature 20° to 25°C (68° to 77°F).

Save this leaflet for future reference.

Innovus Pharmaceuticals, Inc.
373 Inverness Pkwy #206
Englewood , CO 80112 U.S.A.

Label part # REG2002-INS
Label rev. date 02/21



REGOXIDINE

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-542
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-542-03	3 in 1 CARTON	04/19/2021	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	04/19/2021	

Labeler - Innovus Pharmaceuticals Inc. (962507187)

Registrant - Innovus Pharmaceuticals Inc. (962507187)

Revised: 5/2021

Innovus Pharmaceuticals Inc.