

**REGOXIDINE- minoxidil solution**  
**Innovus Pharmaceuticals Inc.**

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**REGOXIDINE (FOR MEN)**

**Active ingredient**

Minoxidil 5% w/v

**Purpose**

Hair regrowth treatment for men

**Use**

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

**Warnings**

**For external use only. For use by men only.**

**Flammable:** Keep away from fire or flame

**Do not use if**

- you are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution 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

### **Keep Out of Reach of Children**

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

### **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.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with minoxidil topical solution 5% for men
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- 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** onday to Friday at 8am to 5pm EST.

Visit our website at [www.innovuspharma.com](http://www.innovuspharma.com)

## **Consumer Information**

### **MEN'S REGOXIDINE EXTRA STRENGTH**

5% Minoxidil Topical Solution, USP

HAIR REGROWTH TREATMENT

Unscented

#### ***Save this leaflet for future reference***

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. Please read this leaflet carefully. It will help you understand how to use Regoxidine Extra Strength and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Regoxidine Extra Strength, you should ask your healthcare professional or call us at +1-800-996-5122. you can also contact us at our website at [www.innovuspharma.com](http://www.innovuspharma.com)

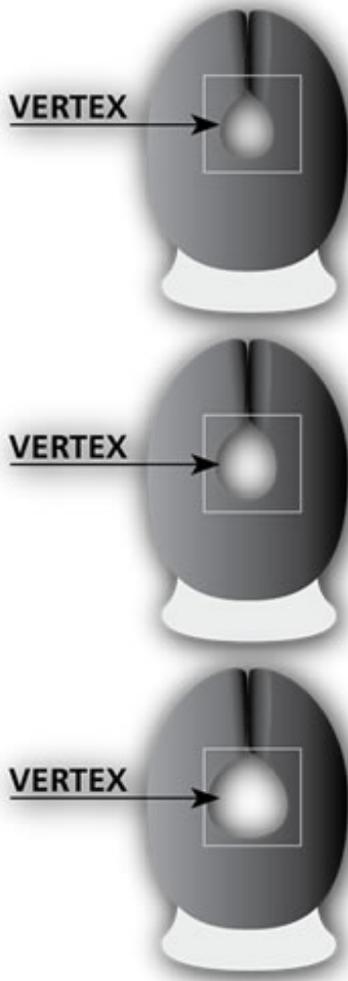
#### **What is Mens' Regoxidine Extra Strength?**

Regoxidine Extra Strength is a colorless liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

#### **Who may use Regoxidine Extra Strength?**

Regoxidine Extra Strength is for use only by men. Regoxidine Extra Strength may be appropriate for you if you are a male at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp (vertex only, as shown on the illustration that follows). It is not intended for frontal baldness or a receding hairline. The common inherited thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Regoxidine Extra Strength is for men with hair loss or thinning hair that begins on the vertex of the scalp. Regoxidine Extra Strength is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Regoxidine Extra Strength may not work.



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

### **Who should not use Regoxidine Extra Strength?**

Women should not use Regoxidine Extra Strength because studies have shown it works no better in women than Women's 2% Minoxidil Topical Solution. Some women may also grow facial hair. In addition, Regoxidine Extra Strength may be harmful if used during pregnancy or breast-feeding.

- Regoxidine Extra Strength should not be used on babies or for children under 18 years old.
- Regoxidine Extra Strength will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp.

Also, Regoxidine Extra Strength 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 Regoxidine Extra Strength work for me?**

The amount of hair regrowth is different for each person. Not everyone will respond to Regoxidine Extra Strength. The response to Regoxidine Extra Strength cannot be predicted. It is unlikely anyone will be able to grow back all their hair. However, to see your best results with Regoxidine Extra Strength, make sure you get the medicine directly to the scalp and apply it twice a day, every day. You may get better results if you have been losing your hair for a short period of time or have little hair loss. However, for some men Regoxidine Extra Strength may not work.

### **How soon can I expect results from using Regoxidine Extra Strength?**

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Regoxidine Extra Strength also takes time. Results may be seen as early as 2 months with twice daily use.

For some men, it may take at least 4 months for results to be seen. If you do not see any results after 4 months, stop using Regoxidine Extra Strength. When you first begin to use Regoxidine Extra Strength, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hairs in order to regrow more new hairs. This temporary increase in hair loss is expected and is a part of the process for how Regoxidine Extra Strength regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

### **What Minimal, Moderate and Dense Hair Regrowth Will Mean for You?**

	<b>Number of Hairs</b>	<b>Hair Density</b>
<b>Minimal</b>	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.
<b>Moderate</b>	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.
<b>Dense</b>	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.

### **If Regoxidine Extra Strength is working, what will the hair look like?**

At first, hair growth is usually soft, downy, colorless hairs (like peach fuzz). 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 Regoxidine Extra Strength?**

If you experience hair regrowth, continued use of Regoxidine Extra Strength is necessary or the hair loss will begin again. In studies with 5% minoxidil topical solution, hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

### **What happens if I completely stop using Regoxidine Extra Strength? Will I keep the new hair?**

Continuous use of Regoxidine Extra Strength is needed to maintain hair regrowth. If you

stop using Regoxidine Extra Strength, you will lose your newly regrown hair in 3 to 4 months.

### **How do I use Regoxidine Extra Strength?**

For best results, apply 1 mL with applicator 2 times a day directly onto the scalp in the hair loss area. Using more or using more often will not improve results. Each bottle should last one month, if used as directed.

Allow time for Regoxidine Extra Strength to dry completely before wearing a hat, or lying on a pillow, etc. Regoxidine Extra Strength may cause staining of clothing or linens if damp on the scalp. When applying Regoxidine Extra Strength at night, be sure to allow 2 to 4 hours to dry completely. Never take this product by mouth or apply to other parts of the body.

### **When do I use Regoxidine Extra Strength?**

Apply Regoxidine Extra Strength once in the morning and once at night. The nighttime application should occur 2 to 4 hours before going to bed to allow for drying. Each bottle should last one month, if used as directed.

### **What if I miss a dose or forget to use Regoxidine Extra Strength?**

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

### **Can I use Regoxidine Extra Strength more than twice a day? Will it work faster, better?**

No. Regoxidine Extra Strength 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 Extra Strength 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 chance of side effects.

### **What kind of shampoo should I use with Regoxidine Extra Strength?**

If you wash your scalp before applying Regoxidine Extra Strength, use a mild shampoo.

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

Yes. Hair sprays, spritz, or styling aids may be used on your hair while using Regoxidine Extra Strength. For best results, Regoxidine Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Regoxidine Extra Strength first, and then applying styling products and style as usual. Keep in mind that your best results will be seen with proper application.

### **Can I have my hair colored or permed or use hair relaxers while using Regoxidine Extra Strength?**

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of Regoxidine Extra Strength. 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 Regoxidine Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply Regoxidine Extra Strength on the same day that you use a chemical treatment on your hair.
3. Do not use Regoxidine Extra Strength 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 Regoxidine Extra Strength as usual.

4. Simply restart your normal Regoxidine Extra Strength routine. There is no need to use more Regoxidine Extra Strength to make up for missed applications. Missing one day of Regoxidine Extra Strength will not affect your hair regrowth results.

### **Can I apply Regoxidine Extra Strength and wash my hair an hour later?**

No. For Regoxidine Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.

### **Directions for Use**

When applying Regoxidine Extra Strength, make sure the medicine comes in direct contact with the scalp. Carefully follow the instructions below to use the child-resistant dropper to apply Men's Regoxidine Extra Strength:

- Remove the bottle of Men's Regoxidine Extra Strength from the carton.
- To remove the child resistant cap, push down and turn in direction of the arrows on the cap. Discard cap after use.
- Remove the dropper from the carton.
- Squeeze the rubber bulb and insert the dropper into the bottle.
- Release the bulb, allowing the dropper to fill to the 1 mL line, squeeze the extra amount back into the bottle.
- Part your hair in the area of hair thinning/loss.
- 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.
- **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 Extra Strength.

- After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

### **Warnings**

**For external use only**

**For use by men only**

**Flammable: Keep away from fire or flame**

### **Do not use if**

- you are a woman
- your amount of hair loss is different than that shown on the other side of this leaflet or your hair loss is on the front of the scalp. Regoxidine Extra Strength 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.
- 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.

### **What are the most common side effects with Regoxidine Extra Strength?**

The most common side effects are itching and skin irritation of the treated area of the scalp. If scalp irritation continues, stop use and see a doctor. Regoxidine Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If Regoxidine Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

### **Can Regoxidine Extra Strength produce unwanted hair growth?**

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair, stop using Regoxidine Extra Strength. Over time, the unwanted hair, if caused by Regoxidine Extra Strength, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

1. limit the application of Regoxidine Extra Strength only to the scalp;
2. if you use your hands to apply Regoxidine Extra Strength, wash your hands well immediately afterwards; and
3. after your nighttime application of Regoxidine Extra Strength, allow enough drying time before going to bed (usually 2 to 4 hours).

### **Can I use Regoxidine Extra Strength for baldness or hair loss in babies or children?**

No. Regoxidine Extra Strength must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your healthcare professional or call toll free **+1-800-996-5122** (collect). You can also visit our website at [www.innovuspharma.com](http://www.innovuspharma.com)

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

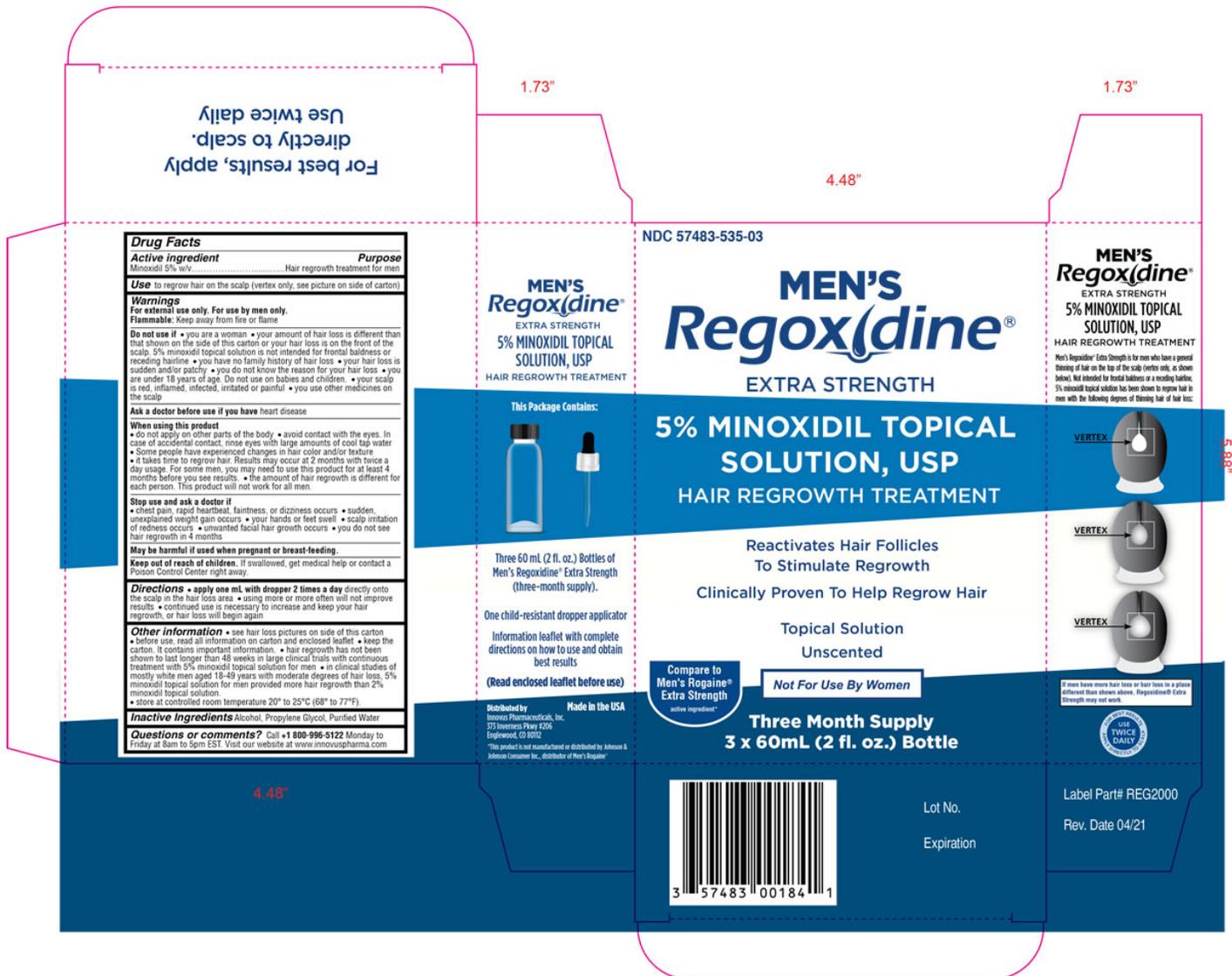
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Innovus Pharmaceuticals, Inc.  
373 Inverness Pkwy #206

Englewood, CO 80112 U.S.A.

Label part # REG2000-INS

Label rev. date 02/21



## REGOXIDINE

minoxidil solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57483-535
<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	3 g in 60 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:57483-535-03	3 in 1 CARTON	05/20/2021	
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	ANDA076239	05/20/2021	

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

Revised: 12/2022

Innovus Pharmaceuticals Inc.