

**REGENPURE PRECISION- minoxidil liquid**  
**Salonceuticals, Inc.**

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**Regenpure Precision Minoxidil**

**Drug Facts**

**ACTIVE INGREDIENT**

Minoxidil, 5% w/v (in each 1mL dose)

**PURPOSE:**

Hair Regrowth Topical Treatment

**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. Minoxidil Topical Solution, 5% 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 medications 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.

**KEEP OUT OF REACH OF CHILDREN**

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

**STOP USE AND ASK DOCTOR IF:**

- Side effects occur: You may report side effects to FDA at 1-800-FDA-1088 or to Salonceuticals, Inc. at 1-877-706-8688
- Chest pain, rapid heartbeat, faintness, or dizziness occurs.
- Sudden, unexplained weight gain occurs.
- Your hands or feet swell.
- Scalp irritation occurs, and continues or worsens.
- Unwanted facial hair growth occurs.

**DIRECTIONS:**

- Apply 1 mL with sprayer (6 sprays) 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 booklet.
- 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%.
- In clinical studies with mostly white men age 18-45 years with moderate degrees of hair loss, Minoxidil Topical Solution, 5% provided more hair regrowth than Minoxidil Topical Solution, 2%.
- Store at USP controlled room temperature 20° to 25°C (68° to 77°F).

**INACTIVE INGREDIENTS:**

- Alcohol 30% v/v, propylene glycol 50% v/v, purified water

**QUESTIONS OR COMMENTS?**

- Call your health professional or Salonceuticals, Inc. at 1-877-706-8688, Monday—Friday: 9:00am—5:00pm (EST)

**Package Labeling:**

**STOP USE AND ASK DOCTOR IF:**

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- Apply 1 mL 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 or hair loss will begin again.

**OTHER INFORMATION:**

- Store at controlled room temperature 20° to 25°C (68° to 77°F).

**INACTIVE INGREDIENTS:**

- Alcohol 30% v/v, propylene glycol 50% v/v, purified water

**DISTRIBUTED BY:**

Salonceuticals, Inc: 877-706-8688  
3148 W Pembroke Rd.  
Hallandale Beach, FL 33009



# Regenepure

Let the Regeneration Begin.

## Precision Minoxidil Spray

Hair Regrowth Spray | Extra Strength for Men  
(5% Minoxidil Topical Solution)

**NOT FOR USE BY WOMEN**

One Month Supply  
1 - 60mL (2 fl. oz) bottle

**Read and keep carton and booklet for full product information.**

**ACTIVE INGREDIENT:** Minoxidil, 5% w/v

**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.
- 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 to 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 or texture.

**Made in the USA**

Mxd. 21

**Regenepure**

# Precision Minoxidil Spray


Hair Regrowth Spray | Extra Strength for Men  
(5% Minoxidil Topical Solution)

Read enclosed booklet before use.

**Regenepure**

# Precision Minoxidil Spray

Hair Regrowth Spray | Extra Strength for Men  
(5% Minoxidil Topical Solution)



Our unique precision applicator makes it easy to reactivate your hair follicles to stimulate regrowth.

Clinically proven to help regrow hair.

One Month Supply  
1 - 60mL (2 fl. oz) bottle

NOT FOR USE BY WOMEN

**Regenepure**

# Precision Minoxidil Spray

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 Solution, 5% has been shown to regrow hair in men with the following degrees of thinning hair or hair loss:



**Directions**

**ACTIVE INGREDIENT & PURPOSE:**  
Minoxidil, 5% w/v (in each 1 mL dose)  
Hair Regrowth Topical Treatment

- Use to regrow hair on the top of the scalp (vertex only; see pictures on side of carton).

**WARNINGS:**

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- For use by men only.
- Flammable: Keep away from fire or flame.

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- You use other medications on the scalp.

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- The amount of hair regrowth is different for each person. This product will not work for all men.

**DISTRIBUTED BY:**  
SalonCeuticals, Inc.  
3148 W. Pembroke Rd.  
Hallandale Beach, FL 33009  
USA, 1-877-706-8688

**(Directions continued)**

**KEEP OUT OF REACH OF CHILDREN**  
If swallowed, get medical help or contact a Poison Control Center right away.

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**DIRECTIONS:**

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**QUESTIONS OR COMMENTS?**

- Call your health professional or SalonCeuticals, Inc. at 1-877-706-8688. Monday—Friday, 9:00am—5:00pm (EST)

**Regenepure**

Read enclosed booklet before use.

This package contains:

One 60 mL (2.0 fl oz) Bottle of RegenepurePR, Extra Strength Minoxidil Precision Regrowth Spray for Men (one month supply).

This package also contains an educational booklet.

More info at:  
[regenepure.com](http://regenepure.com)  
email: [info@regenepure.com](mailto:info@regenepure.com)

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USA, 877-706-8688

MADE IN THE USA  
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REGENPURE PRECISION			
minoxidil liquid			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71290-813
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)		MINOXIDIL	50 mg in 1 mL
<b>Inactive Ingredients</b>			
Ingredient Name			Strength
ALCOHOL (UNII: 3K9958V90M)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0K00R)			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71290-813-02	1 in 1 BOX	03/05/2017	
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	03/04/2017	

**Labeler** - Salonceuticals, Inc. (049002597)

Revised: 3/2017

Salonceuticals, Inc.