

**5% MINOXIDIL SPRAY.- 5% minoxidil spray liquid**  
**Consilii LLC**

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**Active Ingredient**

Minoxidil 5%

**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

For use by men only

**Do not use**

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. Minoxidil topical solution 5% is not intended for frontal baldness or receding hairline.

you have no family history of hair loss

You have no family history of hair loss, 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 it on babies and children

scalp is red, inflamed, infected, irritated, or painful

you use other medicines on the scalp

**When Using**

Do not apply on other parts of the body

avoid contact with eyes. In case of accidental contact, rinse eyes with a large amount 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**

chest pain, rapid heart beat, 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

### **Ask Doctor**

When Pregnant or breast-feeding

If you have heart disease

### **Keep Out Of Reach Of Children**

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

### **Directions**

Apply 5 sprays 2 times a day directly to the scalp in the hair loss area

Using more than directed 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 the carton

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 aerosol 5% for men

in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical aerosol 5% for men provided more hair regrowth than minoxidil topical aerosol 2%

Store at 20 to 25°C (68 to 77°F). Keep tightly closed.

**Inactive ingredients**

Deionized Water, Biotin, Rosemary Oil, Castor Oil, Panthenol, Niacinamide, Aloe Vera Extract, Ethanol, Glycerin

**Questions**

customerservice@avitapure.com

**PRINCIPAL DISPLAY PANEL**

**AvitaPure**  
Hair Regrowth Kit  
FOR MEN

**Drug Facts**

Active ingredient	Purpose
Minoxidil 5% w/w	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  
For use by men only

- Do not use if**
- 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. 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 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.**

**Drug Facts**

**Directions**  
apply one mL (5 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

**Inactive ingredients**  
Biotin, Rosemary Oil, Castor Oil, Panthenol, Niacinamide, Aloe Vera Extract, Ethanol, Glycerin, Deionized Water.

**Other information**  
see hair loss pictures on side of this carton  
before use, read all information on carton  
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, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%  
store at 20-25° C (68-77° F). Keep tightly closed.

**Questions or comments?**  
customerservice@avitapure.com

**Distributed By**  
Elegant Esthetic Inc.  
30 N Gould St Ste R  
Sheridan, WY 82801

**Designed in U.S.A.**  
**Made in PRC**



**AvitaPure**  
MEN'S EXTRA STRENGTH  
**Minoxidil**  
Hair Regrowth Kit

**5% Minoxidil with Biotin Topical Spray**

**#1**  
DERMATOLOGIST  
RECOMMENDED  
ACTIVE INGREDIENT



Revitalizes Hair Follicles

Clinically Proven To Help Regrow Hair

60ml / 2 fl oz



Men's AVITAPURE Extra Strength is for men who have a general thinning of hair on the top of scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline.

Men's AVITAPURE Extra Strength has been shown to regrow hair in men with the following degrees of thinning hair of hair loss.

**Minoxidil**  
Hair Regrowth Kit

If men have more hair loss or hair loss in a place different than shown above, Men's AVITAPURE Extra Strength may not work.

**This Package Contains**  
One 60ml (2 fl oz) Bottle of Men's AVITAPURE Extra Strength  
One 540 Needles of Titanium 0.25mm Derma Roller

**How to Use Derma Roller**

- Wash your hair along with the scalp and allow it to dry
- Sanitize the roller using alcohol
- Gently roll over the area of scalp to be treated in a single direction for 4-6 times
- Gradually alter the directions and repeat the previous step
- Administer the hair regrowth treatment

**Cautions**  
Do not use more than twice a week  
Do not roll too much more than the indicated time  
Do not use hair care products that may irritate your scalp after use  
Do not use if your scalp is red, inflamed, infected, irritated or painful.  
Do not share with another person  
Keep out of reach of children  
This is NOT a medical device. It does not use to treat any illness or disease. It does not alter the form or function of the body.

Batch No: 230815-HC-FG01  
MFG: 08/15/2023  
EXP: 08/15/2025

AvitaPure

MEN'S EXTRA STRENGTH

# Minoxidil Hair Regrowth Kit

## Minoxidil Hair Regrowth Kit

### MAIN INGREDIENTS

5% Minoxidil, Biotin,  
Rosemary Oil, Castor Oil,  
Niacinamide, Panthenol,  
Aloe Vera Extract, Glycerin

### HOW TO USE

**STEP 01** Wash your hair along with the scalp and allow it to dry

**STEP 02** Administer 1ml (5 sprays) directly to the area of scalp to be treated

**STEP 03** Gently massage with your hands for 1-2 minutes until the spray is fully absorbed

**STEP 04** Wash your hands well after styling your hair as usual

5% Minoxidil  
with Biotin  
Topical Spray

#1

DERMATOLOGIST  
RECOMMENDED  
ACTIVE INGREDIENT



Revitalizes  
Hair Follicles

60ml / 2 fl oz

## 5% MINOXIDIL SPRAY.

5% minoxidil spray liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83299-020
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CASTOR OIL (UNII: D5340Y2I9G)	
WATER (UNII: 059QF0KO0R)	
BIOTIN (UNII: 6S06U10H04)	

<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83299-020-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075357	11/01/2023	

**Labeler** - Consilii LLC (118891890)

### Establishment

Name	Address	ID/FEI	Business Operations
Consilii LLC		118891890	label(83299-020) , manufacture(83299-020)

Revised: 11/2023

Consilii LLC