

**GAINEXTRA HAIR REGROWTH TREATMENT FOR MEN 5%- minoxidil 5% spray  
Gabar Health Sciences Corp.**

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**Gainextra-5% Minoxidil Topical Solution, USP**

Minoxidil 5% w/v

Hair regrowth treatment for men

**USE**

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

For external use 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 everyone.
- 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.

## **DIRECTIONS**

- Prim the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist.
  - apply one mL (6 sprays) 2 times a day directly onto the scalp in the area of hair loss
  - 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.
  - see hair loss pictures on side of this carton
  - before use, read all information on carton and enclosed leaflet
  - keep this 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 5% minoxidil topical solution for men
  - in clinical studies of mostly white men aged 18-19 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 between 68°-77°F (20°-25°C).
- alcohol, propylene glycol, purified water

THIS PACKAGE CONTAINS:  
\*1-100ML (3.38 FL.OZ) bottle of Minoxidil Topical  
Spray, 5% for Men (1 month supply)

NDC 82429-261-10

gainextra 

**HOW TO USE**



**STEP 1  
FOR SCALP**  
Apply four direct sprays  
daily onto the scalp



**STEP 2**  
Massage with your hand to evenly  
distribute (apply pressure, so that  
blood flow can increase for scalp).



**STEP 3**  
Massage into scalp with fingers,  
then wash hands well.



**STEP 4**  
Continued use is necessary to  
increase and keep your hair  
regrowth or hair loss will begin again.

**Who should NOT use minoxidil topical solution 5%?**  
Minoxidil topical solution 5% will not prevent or improve hair loss related  
to pregnancy, the use of some prescription and non-prescription  
medications, certain severe medical conditions (very low body iron,  
excessive vitamin A intake), the recently discontinued use of birth control  
pills, low thyroid status (hypothyroidism), chemotherapy, or diseases which  
cause scarring of the scalp.

Manufactured for and distributed by  
Gaber Health Sciences Corp  
1 Horsfield Center Parkway  
Atlanta, GA 30354



# HAIR REGROWTH TREATMENT

REVITALIZES HAIR FOLLICLES

- CLINICALLY PROVEN TO HELP REGROW HAIR
- TOPICAL SOLUTION
- UNSCENTED



1 MONTH SUPPLY  
100ML (3.38 FL.OZ)

**Drug Facts**

| Active ingredient                     | Purpose                         |
|---------------------------------------|---------------------------------|
| Minoxidil 5% w/w (without propellant) | Hair regrowth treatment for men |

**Directions**

- Apply 6 Sprays 2 times a day directly onto the scalp in the area of hair loss
- massage into scalp with fingers, then wash hands well
- continued use is necessary to increase and keep your hair regrowth or hair loss will begin again

**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. (800-222-1222)**

**Inactive ingredients**

alcohol, propylene glycol, purified water

**Questions? Call (1-470-737-9424)**

## GAINEXTRA HAIR REGROWTH TREATMENT FOR MEN 5%

minoxidil 5% spray

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:82429-261 |
| <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         | 5 g in 100 mL |

### Inactive Ingredients

| Ingredient Name                             | Strength |
|---|----------|
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)  |          |
| <b>WATER</b> (UNII: 059QF0KO0R)             |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82429-261-10 | 1 in 1 BOX   | 10/23/2023           |                    |
| 1 |                  | 100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA076239                               | 10/23/2023           |                    |

**Labeler** - Gabar Health Sciences Corp. (118401847)

Revised: 10/2023

Gabar Health Sciences Corp.