

5% MINOXIDIL TOPICAL SOLUTION- minoxidil solution
Gabar Health Sciences Corp.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

5% Minoxidil Topical Solution

Drug Facts

Active Ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

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

Warnings

For external use only.

For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- 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 5% minoxidil topical foam 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. (1-800-222-1222)

Directions

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss picture on side of this carton
- before use, read all information on carton and enclosed leaflet
- keep the carton. It contains important information.
- store at controlled room temperature 20° to 25°C (68° to 77°F)
- contents under pressure. Do not puncture or incinerate container.
- do not expose to heat or store at temperature above 120°F (49°C).

Inactive ingredients

butylated hydroxytoluene, cetyl alcohol, citric acid anhydrous, dehydrated alcohol, isobutane, lactic acid, n-butane, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

- Call **1-470-737-9424**

Manufactured and distributed by:

Gabar Health Sciences Corp., Atlanta, GA 30385

PRINCIPAL DISPLAY PANEL

Minoxidil Topical Aerosol, 5% (For Men)

HAIR REGROWTH TREATMENT

Reactivates hair follicles to stimulate regrowth

Clinically proven to help regrow hair

#1 Dermatologist Recommended Active Ingredient

Easy-to-use-foam unscented

3 MONTH SUPPLY

3 - 60 g (2.11 OZ) CANS

NOT FOR USE BY WOMEN

gainextra

NDC 62429-200-60

MEN'S

gainextra

5% Minoxidil Topical Foam
Hair Regrowth Treatment

Unscented
#1 Dermatologist
Recommended Active Ingredient*

Clinically Proven

FOAM FOR MEN

3 MONTH SUPPLY
3 - 60g (2.11 oz) CANS

Drug Facts

Active Ingredient Purpose
Minoxidil 5% (w/v without propellant) Hair regrowth treatment for men

Use To regrow hair on the top of the scalp (back only), see pictures on side of this carton.

Warnings
For external use only.
Extremely flammable. Avoid fire, flames, or smoking during and immediately following application.
Directions
you are a woman
your amount of hair loss is different than that shown on side of this carton or your hair loss is on the top of the scalp. (5% minoxidil topical foam is not intended for hair loss on the sides or back of the scalp.)
your hair loss is sudden and/or patchy
you do not know the reason for your hair loss
you experience 10 years of balding (diverticuli or alopecia areata) and/or children.
your scalp is red, inflamed, itchy, or painful
you use other medicines on the scalp.
Ask a doctor before you use this hair loss treatment.

When using this product:
do not apply on other parts of the body.
avoid contact with the eyes. In case of accidental contact, close 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 but take a long time. For some people, you may need to use product for at least 12 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:
headache, tight/tingling, numbness, or dizziness occurs
sudden, unexplained weight gain occurs
your hands "tremble"
scalp itching or redness occurs
unusual facial hair growth occurs
you do not see hair regrowth in 6 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 at once (1-800-222-1222).

Directions
apply half a capful 3 times a day to the scalp in the hair loss area.
massage the scalp with fingers, then wash hands well.
use enclosed buffer for complete directions on how to use.
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
hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used this for 6 months.
see hair loss pictures on side of this carton.
before use, read all information on this and enclosed leaflet.
keep the carton. It contains important information.
store at controlled room temperature 20° to 25° (68° to 77°).
contains propellant, butane, and/or other hydrocarbons.
do not expose to heat or flame or temperatures above 120°F (49°F).

Active ingredients
minoxidil, hydrocarbons, propellant, alcohol, other inert ingredients. **Important:** alcohol, isobutane, butane, acetone, polypropylene, propylene sulfide, acrylate, ethyl alcohol.

Questions? Call (1-470-737-8424)

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments please call (1-470-737-8424).

MEN'S

gainextra

5% Minoxidil Topical Foam
Hair Regrowth Treatment

Unscented
#1 Dermatologist
Recommended Active Ingredient*

Clinically Proven

FOAM FOR MEN

3 MONTH SUPPLY
3 - 60g (2.11 oz) CANS

THIS PACKAGE CONTAINS:
*1-60G (2.11 oz) can of Minoxidil Topical Foam, 5% For Men (1 month supply)

DIRECTIONS FOR USE
See information leaflet with complete directions on how to use and obtain best results.

1: PREP HANDS WITH COLD WATER
Rinse your fingers in cold water and dry them. Note: Foam will melt on contact with warm surfaces.

2: OPEN CHILD RESISTANT CAP
Be sure to align arrow on the cap with arrow on white ring. Tilt cap back and pull off.

3: DISPENSE VERTICALLY ONTO A COLD SURFACE
Hold the can straight upside down. If you hold the can at an angle, foam may not dispense properly. Press nozzle to dispense half a capful of foam onto cold surface (e.g. dish, or cold hands).

4: APPLY TO SCALP, NOT HAIR
Part your hair to expose hair loss area. Massage foam into scalp, not hair. Repeat until all hair loss areas have been covered.

5: CLOSE CAP AND WASH HANDS
Snap cap back into place. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.

Who should NOT use minoxidil topical solution 5%?
Minoxidil topical solution 5% will not prevent or improve hair loss unless properly prepared. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.

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5% MINOXIDIL TOPICAL SOLUTION

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82429-200
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEHYDRATED ALCOHOL (UNII: 3K9958V90M)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID (UNII: 33X04XA5AT)	
BUTANE (UNII: 6LV4FOR43R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	white (white to off-white foam)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82429-200-60	60 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/10/2022	

Labeler - Gabar Health Sciences Corp. (118401847)

Registrant - Gabar Health Sciences Corp. (118401847)

Establishment

Name	Address	ID/FEI	Business Operations
Gabar Health Sciences Corp.		118401847	manufacture(82429-200)

Revised: 11/2022

Gabar Health Sciences Corp.