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 baldmess 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 directons 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 20º to 25ºC (68º to 77ºF)
- contents under pressure. Do not puncture or incinerate container.
- do not expose to heat or store at temperature above 120ºF (49ºC).

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

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.