

FOLLICLE FOLLIXIL 5% MINOXIDIL HAIR REGROWTH-LOTION- follicle follixil 5% minoxidil hair regrowth-lotion liquid
Guangzhou Ariel Biotech Co., Ltd.

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.

Active Ingredient(s)

Minoxidil 5%

Purpose

Hair regrowth treatment for men.

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

- 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 medicines on the scalp.

- 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.

- 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 one mL with dropper 2 times a day directly onto the scalp in the hair loss area.
- Using more or more often will not improve results.
- Continuous use is necessary to increase and keep your hair regrowth, or hair loss will begin again.

Other information

1. See hair loss pictures on side of this carton.
2. Before use, read all information on carton and enclosed leaflet.
3. Keep the carton. It contains important information.
4. 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.
5. In clinical studies with mostly white men aged between 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%.
6. Store at 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients

Water, Alcohol, Propylene Glycol, Glycerol, Biotin, Caffeine, Niacinamide

Package Label - Principal Display Panel



FOLLICLE FOLLIXIL 5% MINOXIDIL HAIR REGROWTH-LOTION

follicle follixil 5% minoxidil hair regrowth-lotion liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84148-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
BIOTIN (UNII: 6S06U10H04)	
NIACINAMIDE (UNII: 25X5118RD4)	
CAFFEINE (UNII: 3G6A5W338E)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84148-005-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/17/2024	

Labeler - Guangzhou Ariel Biotech Co., Ltd. (402818771)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Ariel Biotech Co., Ltd.		402818771	manufacture(84148-005)

Revised: 4/2024

Guangzhou Ariel Biotech Co., Ltd.