

**FOLLINIQUE- minoxidil solution**  
**Premium Distribution, LLC**

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**Follinique**

**Active ingredients:**

**Minoxidil 2.0% w/v**

**Purpose**

**Hair regrowth treatment**

**Use**

to regrow hair on the scalp

**Warnings**

**For external use only.**

**Flammable:** Keep away from fire or flame

**Do not use if**

- your degree of hair loss is different than that shown on the side of this carton, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- 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 medications 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. You may need to use this product 2 times a day 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

**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

**If pregnant or breast feeding, ask a health professional before use.**

**Keep out of reach of children.**

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

### **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
- 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 carton and enclosed leaflet
- in clinical research in mostly white women age 18-45 years with mild to moderate degrees of hair loss, the following response to Minoxidil Topical Solution 2% was reported: 19% of women reported moderate hair regrowth after using women's Minoxidil Topical Solution 2% for 8 months; 19% had moderate regrowth; 40% had minimal regrowth. This compares with 7% of women reporting hair regrowth after using the placebo, the liquid without Minoxidil in it, for 8 months (7% had moderate regrowth, 33% had minimal regrowth)
- keep the carton. It contains important information.
- store at controlled room temperature 20<sup>0</sup> to 25<sup>0</sup>C (68<sup>0</sup> to 77<sup>0</sup>F).

### **Inactive Ingredients:**

alcohol , propylene glycol, purified water.

### **Questions or comments?**

877-279-9024

Visit website at [www.follinique.com](http://www.follinique.com)

NDC 70788-579-01

Follinique

Women's 2% Minoxidil Topical Solution USP

Hair Regrowth Treatment

Reactivates Hair Follicles to Stimulate Regrowth

Clinically Proven to Help Regrow Hair

Unscented Topical Solution

FOR BEST RESULTS APPLY DIRECTLY TO SCALP.  
USE TWICE DAILY.

NDC 70788-579-01

# FOLLINIQUE

## WOMEN'S 2% Minoxidil Topical Solution USP

### HAIR REGROWTH TREATMENT

REACTIVATES HAIR FOLLICLES TO STIMULATE  
REGROWTH.

CLINICALLY PROVEN TO HELP REGROW HAIR.  
UNSCENTED TOPICAL SOLUTION

One 60 ml (2 fl oz) Bottle | One Month Supply

### Drug Facts

**Active Ingredient** Minoxidil 2% w/v. **Purpose** Hair regrowth treatment

**Use** to regrow hair on the scalp

#### Warnings

For external use only.

**Flammable:** Keep away from fire or flame

Do not use if: • your degree of hair loss is different than that shown on the side of this carton, because this product may not work for you • you have no family history of hair loss • your hair loss is sudden and/or patchy • your hair loss is associated with childbirth • 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, 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. You may need to use this product 2 times a day 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

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.

**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 • continued use unnecessary to increase and keep your hair regrowth, or hair loss will begin again

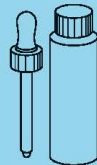
**Other information** • see hair loss pictures on side of this carton • before use, read all information on carton and enclosed leaflet • keep the carton. It contains important information. • In clinical studies of mostly white women aged 18 - 45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil in 1 for 8 months (7% had moderate regrowth; 33% had minimal regrowth) • store at controlled room temperature 20° to 25°C (68° to 77°F).

**Inactive ingredients** Alcohol, Propylene Glycol, Purified Water

**Questions or comments?** 877-279-9024

• Visit Website at WWW.FOLLINIQUE.COM

#### THIS PACKAGE CONTAINS



One 60 ml (2 fl oz) Bottle of Women's FOLLINIQUE (one month supply) One child-resistant dropper applicator. Information leaflet with complete directions on how to use and obtain best results.

**DISTRIBUTED BY: FOLLINIQUE**  
PO BOX 52126, Phoenix, AZ 85072  
877-279-9024

MADE IN USA

Women's FOLLINIQUE is for women who have a general thinning of hair on the top of the scalp as shown. Women's FOLLINIQUE has been shown to regrow hair in women with the following degrees of thinning hair or hair loss:



If women have more hair loss or hair loss in a place different than shown above, Women's FOLLINIQUE may not work.

Do not use if you have patchy hair loss as shown below.



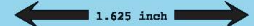
MADE IN USA



Lot No.

Expiration

K/O for coating will not print



## FOLLINIQUE

minoxidil solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70788-579
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

ALCOHOL (UNII: 3K9958V90M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70788-579-01	1 in 1 CARTON	10/27/2016	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	10/27/2016	

**Labeler** - Premium Distribution, LLC (079805390)

Revised: 4/2017

Premium Distribution, LLC