

RE-GRO- minoxidil solution
Empress Hair Products, Ltd.

Drug Facts

Active ingredient

Minoxidil, USP 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 more 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 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 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

- part your hair and apply with dropper one mL 2 times a day directly onto the scalp in the area of hair thinning/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

Other information

- 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.
- in clinical studies of mostly white women aged 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 minoxidil topical solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients alcohol (60% v/v), propylene glycol, purified water

Questions? 1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

————**Package Label.Principal Display Panel**————

NDC 60900-555-30

Compare to the active ingredient
in Women's Rogaine®*

EMPRESS®

Re-Gro™ Hair Products for Women of Color

**Hair Regrowth
Treatment**

**Minoxidil Topical
Solution,
USP 2%
FOR WOMEN**

Unscented

Clinically Proven to
Help Regrow Hair

Revitalized Hair Follicles

Three Month Supply
3-60 mL (2 fl oz) Bottles



RE-GRO
minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60900-555
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:60900-555-10	1 in 1 CARTON		
1		60 mL in 1 BOTTLE		
2	NDC:60900-555-20	2 in 1 CARTON		
2		60 mL in 1 BOTTLE		
3	NDC:60900-555-30	3 in 1 CARTON		
3		60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074588	04/01/2014	

Labeler - Empress Hair Products, Ltd. (175791966)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmaceuticals Limited Canada		248761249	manufacture(60900-555)

Revised: 11/2014

Empress Hair Products, Ltd.