

EXT HAIR REGROWTH TREATMENT FOR WOMEN- minoxidil 2% solution ITEM, LLC

EXT Hair Regrowth Treatment for Women

USE

Use to regrow hair on the scalp

Hair regrowth treatment

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree of hair loss is different than 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 or 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

- 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 everyone.

Stop use and ask a doctor if

■ side effects occur. You may report side effects to FDA at

1.800.FDA.1088

■ 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 is necessary to increase and keep your hair regrowth, or hair loss will begin again

- See hair loss pictures on the 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 moderate degrees of hair loss, the following responses 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 hair regrowth). This compares with the 7% of women reporting moderate hair regrowth after using a 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)

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water



HC - Women Box 2% Minoxidil - 07/2019

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minoxidil 2% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 70150-001
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70150-001-01	1 in 1 BOX	09/10/2019	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	09/10/2019	

Labeler - TTEM, LLC (079997910)

Revised: 1/2023

TTEM, LLC