

EXT HAIR REGROWTH TREATMENT FOR MEN 5% - minoxidil 5% solution TTEM, LLC

EXT Hair Regrowth Treatment for Men 5%

Minoxidil 5% w/v

Hair regrowth treatment for men

USE

Use to regrow hair on the top of the scalp (vertex only, see pictures on side of carton)

Warnings

For external use only

Flammable: Keep away from fire or flame

Do not use if

- 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. EXT Hair Regrowth Treatment 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

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 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

Directions

■ apply one mL with dropper 2 times a day directly onto the scalp in the area of hair 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

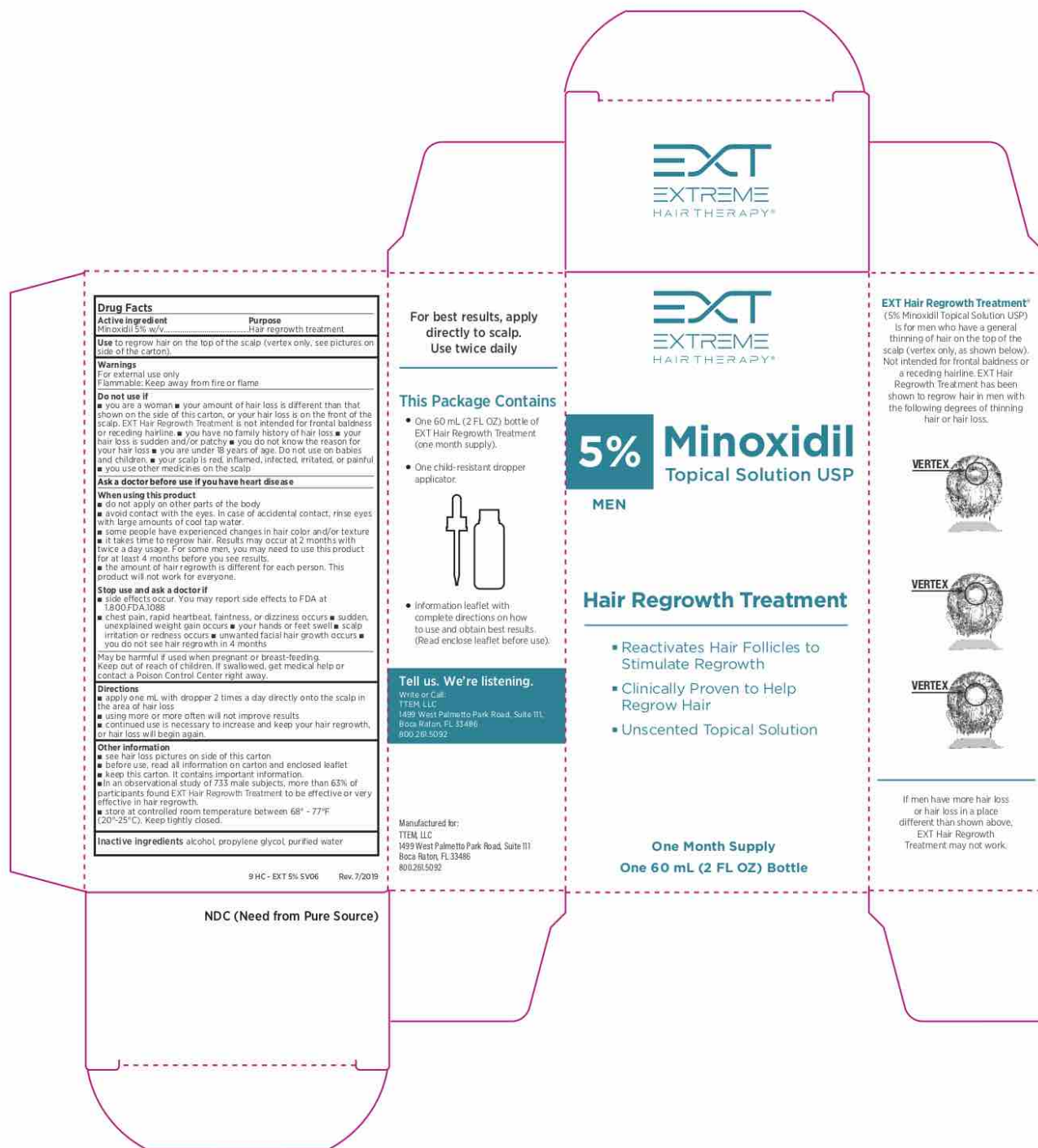
■ keep this carton. It contains important information.

■ In an observational study of 733 male subjects, more than 63% of participants found EXT Hair Regrowth Treatment to be effective or very effective in hair regrowth.

■ store at controlled room temperature between 68° - 77°F (20°-25°C). Keep tightly closed.

Inactive ingredients

alcohol, propylene glycol, purified water



HC - Men Box 5% Minoxidil - 07/2019

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minoxidil 5% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 150-003
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70150-003-01	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	ANDA076239	09/10/2019	

Labeler - TTEM, LLC (079997910)

Revised: 9/2019

TTEM, LLC