

5% MINOXIDIL TOPICAL SOLUTION- minoxidil solution
AVACOR PRODUCTS, LLC

AVACOR - 5% Minoxidil Topical Solution, USP

Minoxidil 5% w/v

Hair regrowth treatment

Use to regrow hair on the scalp

For external use only, For use by men only.

Flammable: Keep away from fire or flame

- 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, 5% minoxidil topical solution 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, 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 all men.

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

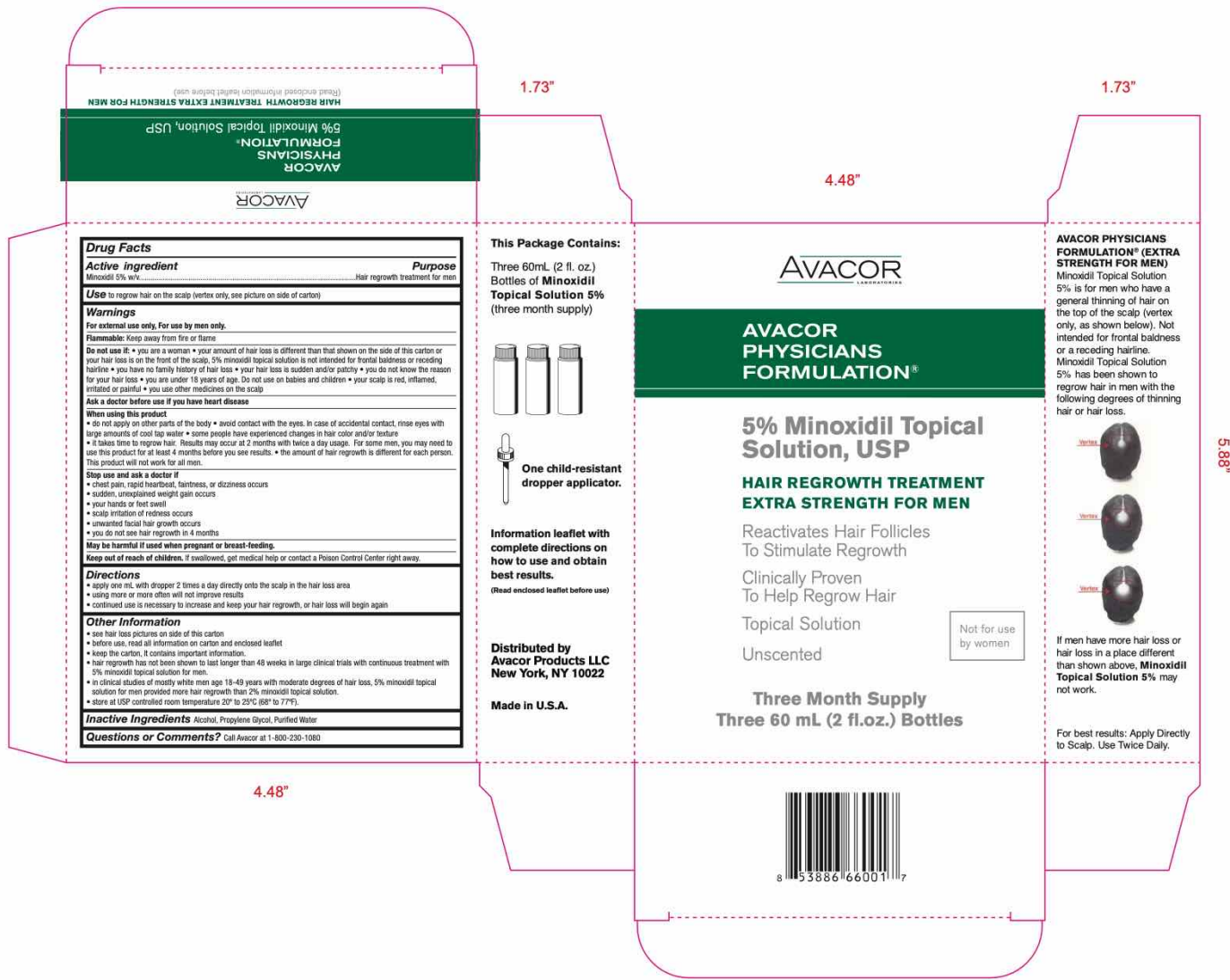
Other Information

- see hair loss pictures on side of this carton
- before use, read all information on carton and enclosed leaflet
- keep the carton, It contains important information.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men.
- in clinical studies of mostly white men age 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution.
- store at USP controlled room temperature 20° to 25°C (68° to 77°F).

Inactive Ingredients: Alcohol, Propylene Glycol, Purified Water

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minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49539-001
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49539-001-01	3 in 1 CARTON	04/01/2019	
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	04/01/2019	

Labeler - AVACOR PRODUCTS, LLC (080364950)**Registrant** - AVACOR PRODUCTS, LLC (080364950)

Revised: 1/2023

AVACOR PRODUCTS, LLC