

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

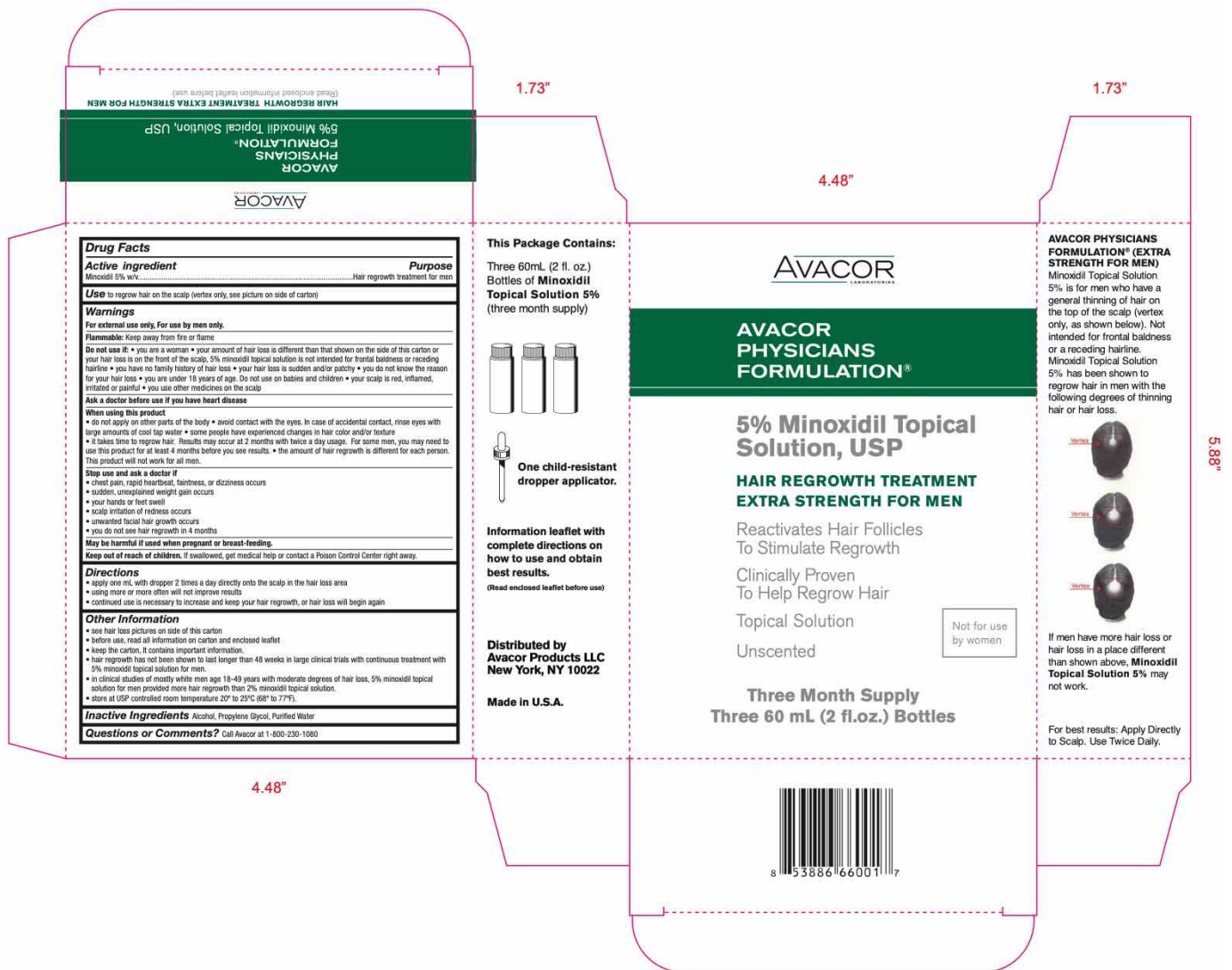
Other Information

- 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

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



Drug Facts

Active ingredient	Purpose
Minoxidil 5% w/v	Hair regrowth treatment for men

Use To regrow hair on the scalp (vertex only, see picture on side of carton)

Warnings
For external use only. For use by men 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. 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

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 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

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Inactive Ingredients: Alcohol, Propylene Glycol, Purified Water

Questions or Comments? Call Avacor at 1-800-230-1080

This Package Contains:

Three 60mL (2 fl. oz.) Bottles of **Minoxidil Topical Solution 5%** (three month supply)

One child-resistant dropper applicator.

Information leaflet with complete directions on how to use and obtain best results.
(Read enclosed leaflet before use)

Distributed by Avacor Products LLC
New York, NY 10022

Made in U.S.A.

AVACOR PHYSICIANS FORMULATION® (EXTRA STRENGTH FOR MEN)
Minoxidil Topical Solution 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil Topical Solution 5% has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

AVACOR PHYSICIANS FORMULATION® (EXTRA STRENGTH FOR MEN)
5% Minoxidil Topical Solution, USP
HAIR REGROWTH TREATMENT EXTRA STRENGTH FOR MEN

Reactivates Hair Follicles To Stimulate Regrowth
Clinically Proven To Help Regrow Hair
Topical Solution
Unscented

Not for use by women

Three Month Supply
Three 60 mL (2 fl. oz.) Bottles

If men have more hair loss or hair loss in a place different than shown above, **Minoxidil Topical Solution 5%** may not work.

For best results: Apply Directly to Scalp. Use Twice Daily.



5% MINOXIDIL TOPICAL SOLUTION

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: 059QF0K00R)	

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: 4/2019

AVACOR PRODUCTS, LLC