MENS PURA DOR HAIR LOSS MD- minoxidil 5% solution Vitals International Group

Vital's International - Men's pura d'or Hair Loss Treatment

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) 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

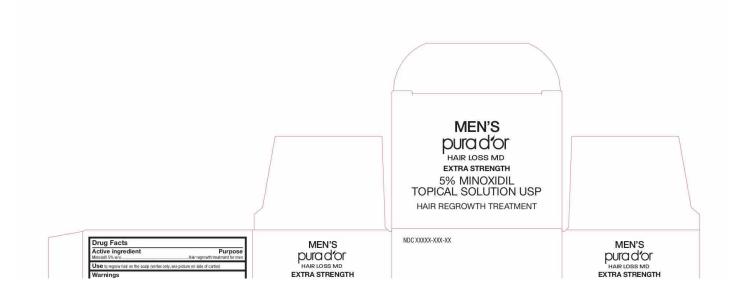
May be harmful if used when pregnant or breast-feeding.

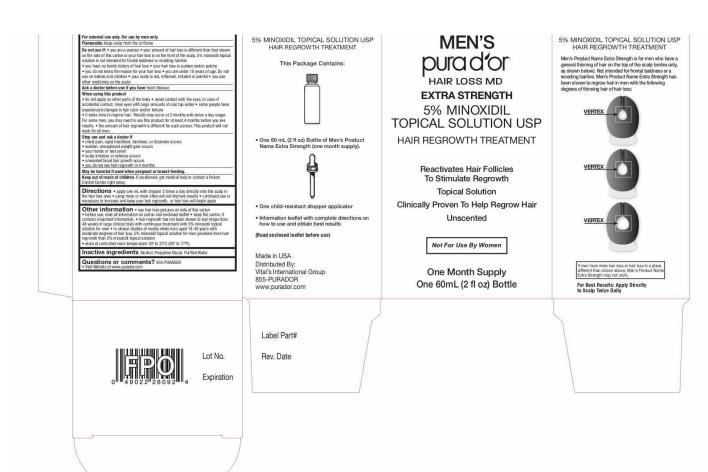
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

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 aged 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 controlled room temperature 20° to 25°C (68° to 77°F). Alcohol, Propylene Glycol, Purified Water Questions or comments? 855-PURADOR
- Visit Website at www.purador.com





MENS PURA DOR HAIR LOSS MD

minoxidil 5% solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69019-001
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	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69019-001- 01	1 in 1 BOX	09/27/2019	
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	09/27/2019	

Labeler - Vitals International Group (049656991)

Revised: 1/2023 Vitals International Group