

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



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, dizziness, 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 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).
Inactive ingredients Alcohol, Propylene Glycol, Purified Water
Questions or comments? 855-PURADOR
 Visit Website at www.purador.com

5% MINOXIDIL TOPICAL SOLUTION USP
 HAIR REGROWTH TREATMENT

This Package Contains:



• One 60 mL (2 fl oz) Bottle of Men's Product Name Extra Strength (one 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)

Made in USA
 Distributed By:
 Vital's International Group
 855-PURADOR
www.purador.com

MEN'S
pura d'or
HAIR LOSS MD
EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION USP
HAIR REGROWTH TREATMENT

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

Not For Use By Women

One Month Supply
 One 60mL (2 fl oz) Bottle

5% MINOXIDIL TOPICAL SOLUTION USP
 HAIR REGROWTH TREATMENT

Men's Product Name Extra Strength 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. Men's Product Name Extra Strength has been shown to regrow hair in men with the following degrees of thinning hair of hair loss:



If men have more hair loss or hair loss in a place different than shown above, Men's Product Name Extra Strength may not work.

For Best Results: Apply Directly to Scalp Twice Daily



Lot No.
 Expiration

Label Part#

Rev. Date

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: 059QF0K00R)	

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