

PACINOS 5 MINOXIDIL TOPICAL SOLUTION- minoxidil liquid
PACINOS SIGNATURE INC

PACINOS 5% Minoxidil Topical Solution

Drug Facts

Active Ingredient

Minoxidil 5% w/v

Purpose

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 women
- 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

- prime the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist
- **apply one mL with spray (6 sprays) 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 18-45 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?

1-877-824-4538

- Visit Website at www.pacinosignatureline.com

Package Labeling:

3.125"

Drug Facts	
Active Ingredient Minoxidil 5% w/v	Purpose Hair regrowth treatment for men
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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	
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MEN'S
PACINOS
SIGNATURE LINE
EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION, USP
HAIR REGROWTH TREATMENT

NDC XXXXX- XXX-X

MEN'S
PACINOS
SIGNATURE LINE
EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION, USP
HAIR REGROWTH TREATMENT

With child-resistant Sprayer pump applicator

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

Made In U.S.A.

Distributed By:
PACINOS SIGNATURE, INC
BOCA RATON, FL, 33487

Add Label part #
Rev.

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

3.125"

MEN'S
PACINOS
SIGNATURE LINE
EXTRA STRENGTH
5% MINOXIDIL
TOPICAL SOLUTION, USP
HAIR REGROWTH TREATMENT

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 of hair loss

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**

Lot No.
Expiration Date:

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3.125"

Add image transcription here...

PACINOS 5 MINOXIDIL TOPICAL SOLUTION			
minoxidil liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83383-398
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83383-398-00	1 in 1 BOX	04/10/2023	
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	04/10/2023	

Labeler - PACINOS SIGNATURE INC (069772244)

Revised: 4/2023

PACINOS SIGNATURE INC