

MYHAIR HAIR REGROWTH TREATMENT- minoxidil 5% solution
APV Life Sciences, LLC

myhair 5% Minoxidil Topical Solution, USP

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, infected, 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

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

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

DIRECTIONS

- Apply 1 mL two times a day directly onto the scalp in the area of hair loss
- 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.
 - See hair loss pictures on side of this carton
 - Before use, read all information on carton and enclosed leaflet
 - Keep this 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 18-19 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 between 20°-25°C (68° - 77°F).

Alcohol, Propylene Glycol, Purified Water

Questions or comments? +1 (415) 483-9399

- Visit Website at www.myhair.life

0

880 06640

VC20-0664D

8 60005 50020 7

Drug Facts

Active Ingredient Minoxidil 5% **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 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 to 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 6 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, lightheadedness, 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 6 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 1 mL, two 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 maintain 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 newly thinning 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? • 1 (415) 483-9399
• Visit Website at www.myhairfile

5% MINOXIDIL TOPICAL SOLUTION
Hair regrowth treatment

THIS PACKAGE CONTAINS:
Three 60 mL (2 fl oz) Bottles of Minoxidil Topical Solution 5% (three months supply)

One child-resistant dropper applicator

Information leaflet with complete directions on how to use and obtain best results

Read enclosed leaflet before use.

FOR BEST RESULTS
Apply directly to scalp twice daily.

Made in the USA
Manufactured for:
APV Life Sciences, LLC
2810 N Church Street, PWB 79535
Wilmington, Delaware
19880-4447, USA

myhair

NDC XXXXX-XXX-XX

5% Minoxidil Topical Solution, USP

Hair regrowth treatment

Clinically proven to help regrow hair

Reactivates hair follicles to stimulate regrowth

Unscented

Topical Solution

not for use by women

Three Months Supply
Three 60 mL (2 fl oz) Bottles

5% MINOXIDIL TOPICAL SOLUTION
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:

00000-0

5% MINOXIDIL TOPICAL SOLUTION
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.

VISTA COLOR®	
Company Pure Source	Component size 10.781" X 13.031" Colors
Part Number PURSO-3_BOTTLE_MINOXIDIAL_P	
Overs/Unders	
Caliper	
Stock	Black 419
Coating	0.38% 3.11% 0.37%
Previous VC Number	Spot Coatings Special Finishes
Die Number VC20-0664D.ARD	
Comments (Reason for the change)	
Proof Number	Date
<input type="checkbox"/> No Varnish Area	<input type="checkbox"/> Coating
<input type="checkbox"/> Cut <input type="checkbox"/> Partial Cut <input type="checkbox"/> Crease <input type="checkbox"/> Bleed	<input type="checkbox"/> Ink Type
<input type="checkbox"/> Blanket <input type="checkbox"/> Cyrel <input type="checkbox"/> Hybrid <input type="checkbox"/> Foil <input type="checkbox"/> Emboss <input type="checkbox"/> Braille	<input type="checkbox"/> Technical Inks
OPERATOR hespindola Date 10/20/2020 12:22:06QC	ACUVAS Date 10/20/2020 12:22:06QC
REP / CSR	Customer Approval Date
<input type="checkbox"/> Mock-Up? User: Date:	Trap Type: Normal
QC: Date:	Black KD: No
	Global Vision: Overridden

MYHAIR HAIR REGROWTH TREATMENT

minoxidil 5% solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81718-001

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:81718-001-01	3 in 1 BOX	03/24/2021	
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	03/24/2021	

Labeler - APV Life Sciences, LLC (117679983)

Revised: 1/2023

APV Life Sciences, LLC