

REGEN- 5% minoxidil topical solution solution
Premium Distribution, LLC

Drug Facts

Active ingredient

Minoxidil USP 5% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures 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, 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 part of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some individuals (people) have experienced changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with 2 times daily usage of this product. 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
- you get unwanted facial hair growth
- 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 1 mL with sprayer (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 booklet.
- 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 solutions for men.
- In clinical studies with 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?

Call your health professional or Follinique at 888-508-0320 Monday - Friday 9:00 AM - 5:00 PM (MST)

Regen by Follinique

Men's 5% Minoxidil Topical Solution, USP

Extra Strength For Men

Hair Regrowth Treatment

Reactivates hair follicles to stimulate regrowth

Clinically proven to help regrow hair

Unscented Topical Solution

Not for use by women

One 60 mL (2 fl oz) Bottle / One month supply

EXTRA STRENGTH
HAIR REGROWTH
TREATMENT
Topical Solution, USP
5% Minoxidil

Drug Facts

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

Use to regrow hair on the top of the scalp (vertex only, see pictures on side of carton).

Warnings

For external use only.

For use by men only.

Hammhshh: 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. Minoxidil Topical Solution, 5% 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.

May be harmful if 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 1 mL with sprayer (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.

Drug Facts (continued)

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 Minoxidil Topical Solution, 5%.
- in clinical studies with mostly white men age 18-49 years with moderate degrees of hair loss, Minoxidil Topical Solution, 5% for men provided more hair regrowth than Minoxidil Topical Solution, 2%.
- store at controlled room temperature 20° to 25°C (68° to 77°F).

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

Questions or comments?

Call your health professional or Follinique at 888-508-0320 Monday – Friday, 9:00 AM – 5:00 PM (MST)

THIS PACKAGE CONTAINS



- One 60 mL (2 fl oz) bottle of Men's (one month supply) with child-resistant sprayer pump applicator.
- Information leaflet with complete directions on how to use and obtain best results.

DISTRIBUTED BY: FOLLINIQUE

PO BOX 62126, Phoenix, AZ 85072
888-508-0320

MADE IN USA

RéGEN
by FOLLINIQUE

MEN'S
5% Minoxidil
Topical Solution, USP

EXTRA STRENGTH
FOR MEN

HAIR REGROWTH TREATMENT

REACTIVATES HAIR FOLLICLES
TO STIMULATE REGROWTH
CLINICALLY PROVEN TO HELP
REGROW HAIR
UNSCENTED TOPICAL SOLUTION

NOT FOR USE BY WOMEN

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

5% Minoxidil
Topical Solution, USP

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.



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 use twice daily. Apply directly to scalp.

REGEN

5% minoxidil topical solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70788-580
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70788-580-01	1 in 1 CARTON	12/01/2016	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	12/01/2016	

Labeler - Premium Distribution, LLC (079805390)

Revised: 4/2017

Premium Distribution, LLC