

Example Drug Facts Label for Minoxidil Topical Solution 5% for Men

Drug Facts

Active ingredient

Purpose

Minoxidil 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.

Flammability warning: Keep away from fire or flame [Include if product meets the criteria in 16 CFR 1500.3(b)(10)]

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
 - # 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.
 - # scalp is red, inflamed, infected, irritated, or painful
 - # you use other medicines on the scalp
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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.
 - # 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.
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Stop use and ask a doctor if

- # chest pain, rapid heart beat, 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
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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 [may use the numeral 1 here instead of one] mL with dropper or sprayer [insert number of sprays] [include sprayer information if a sprayer is included with the product] 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
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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.
 - # clinical research in mostly white men aged 18-49 years with moderate degrees of hair loss, showed that minoxidil topical solution 5% for men provides more hair regrowth than minoxidil topical solution 2% for men. Hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials with minoxidil topical solution 5% for men.
 - # optional - storage conditions [that are appropriate for the product in both ^oC and ^oF]
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Inactive ingredients [list ingredients in alphabetical order; list alcohol as % v/v]

Questions or comments? call toll free **1-800-XXX-XXXX**

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.