

Example Drug Facts Label for Minoxidil Topical Solution 2% for Men and Women

Drug Facts

Active ingredient	Purpose
Minoxidil 2% w/v.....	Hair regrowth treatment

Use

to regrow hair on the scalp

Warnings

For external use 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

- # your degree of hair loss is more than that shown on the side of this carton. Minoxidil topical solution 2% may not work.
 - # you have no family history of hair loss
 - # hair loss is sudden and/or patchy
 - [Use for products for women]# hair loss is associated with childbirth
 - # 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. You may need to use this product 2 times a day 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 everyone.
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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 [insert 8 for products for women and insert 12 for products for men] months

[Use for products for women] **If pregnant or breast-feeding**, ask a health professional before use.

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

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.

[Use for products for men] in clinical studies of mostly white men aged 18-45 years with moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 26% of men reported moderate to dense hair regrowth after using minoxidil topical solution 2% for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).

[Use for products for women] in clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

optional - storage conditions [that are appropriate for the product in both ^oC and ^oF]

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.