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

Drug Facts

Active ingredient
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

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.

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 °C and °F]

**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.