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

Drug Facts

Active ingredient
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

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.

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

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

**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 °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.