KEEPS MINOXIDIL TOPICAL SOLUTION, 5%- minoxidil solution solution Keeps (30 Madison)

Keeps Minoxidil Topical Solution USP, 5%

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 this 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 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 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. (1-800-222-1222)

Directions

- apply one mL with dropper 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 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 5% minoxidil topical solution for men
- In clinical studies with mostly white men aged 18 to 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 (28.86% v/v), propylene glycol, purified water

Made in Israel

Distributed by:

Thirty Madison, Inc. New York, NY 10016

Questions?

Call toll-free 1-866-923-4914

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton



KEEPS MINOXIDIL TOPICAL SOLUTION, 5%

minoxidil solution solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71713-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)
MINOXIDIL 5965120SH1) MINOXIDIL 50 mg in 1 mL

Inactive Ingredients

Ingredient Name Strength
WATER (UNII: 059QF0KO0R)

ALCOHOL (UNII: 3K9958V90M)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Packaging

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|-------------|----------------------|--|-------------------------|-----------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:71713- 102-09 | 3 in 1 CARTON | 08/31/2025 | | | | |
| 1 | NDC:71713- 102-04 | 60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | | | | |

| Marketing Information | | | | | | | | |
|-----------------------|---------------------------------|-----------------|---------------|--|--|--|--|--|
| Marketing I | Application Number or Monograph | Marketing Start | Marketing End | | | | | |
| Category | Citation | Date | Date | | | | | |
| ANDA | ANDA217998 | 08/31/2025 | | | | | | |
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Labeler - Keeps (30 Madison) (080774087)

| Establishment | | | | | | | | |
|-------------------------------------|---------|-----------|----------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Taro Pharmaceutical Industries Ltd. | | 600072078 | manufacture(71713-102) | | | | | |

Revised: 8/2025 Keeps (30 Madison)