

HEAD AND SHOULDERS SCALP X MINOXIDIL HAIR REGROWTH TREATMENT FOR MEN- minoxidil solution

The Procter & Gamble Manufacturing Company

Head & Shoulders Scalp X Minoxidil Hair Regrowth Treatment for Men

Drug Facts

Active ingredient

Minoxidil 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 carton)

Warnings

For external use 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 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
- 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 minoxidil topical solution 5% for men
- in clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%
- store at 20-25° C (68-77° F). Keep tightly closed.

Inactive ingredients

alcohol, propylene glycol, purified water

Questions or comments?

1-800-723-9569

DIST. BY PROCTER & GAMBLE

CINCINNATI OH 45202.

PRINCIPAL DISPLAY PANEL - Carton

Head & Shoulders

SCALP X

MINOXIDIL

TOPICAL SOLUTION USP, 5%

HAIR REGROWTH

TREATMENT

FOR MEN

Extra Strength Topical Solution

CLINICALLY PROVEN TO HELP REGROW HAIR

Reactivates Hair Follicles to Stimulate Regrowth

Three month supply

Unscented

3 - 60 mL (2 FL OZ) BOTTLES

TOTAL 180 mL (6 FL OZ)



HEAD AND SHOULDERS SCALP X MINOXIDIL HAIR REGROWTH TREATMENT FOR MEN

minoxidil solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69423-559 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1) | MINOXIDIL | 5 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| DEHYDRATED ALCOHOL (UNII: 3K9958V90M) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69423-559-01 | 3 in 1 CARTON | 01/15/2023 | |
| 1 | | 60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091344 | 01/15/2023 | |

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 9/2024

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