

**HEAD AND SHOULDERS SCALP X MINOXIDIL HAIR REGROWTH TREATMENT
FOR MEN- minoxidil aerosol, foam
The Procter & Gamble Manufacturing Company**

Head & Shoulders Scalp X Minoxidil Hair Regrowth Treatment for Men
Drug Facts

Active ingredients

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

- to regrow hair on the top of the scalp (vertex only, see picture on side of this carton)

Warnings

For external use only. For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

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 Aerosol, 5% (Foam) 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

Ask a doctor or pharmacist before use if you are taking any other drugs

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 useage.

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 half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss pictures on side of this carton
- before use, read all information on package and enclosed leaflet
- keep the package. It contains important information
- store at 20-25° C (68-77° F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120° F (49° C)

Inactive ingredients

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, dehydrated alcohol.
isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Questions?

1-800-723-9569

DIST. BY PROCTER & GAMBLE

CINCINNATI OH 45202.

PRINCIPAL DISPLAY PANEL - Carton

Head & Shoulders

SCALP X

MINOXIDIL

TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH

TREATMENT

FOR MEN

CLINICALLY PROVEN TO HELP REGROW HAIR

Reactivates hair follicles to stimulate regrowth

Once-a-day foam for women

Six month supply

Unscented

3 CANS - 2.11 OZ (60 g) EACH

Drug Facts

Active ingredient	Purpose
Minoxidil 5% w/w (without propellant)	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.
Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

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 Aerosol, 5% (Foam) 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, itchy, 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
- swollen, 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. (1-800-525-1222)

Directions:

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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:

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair top pictures on side of this carton
- before use, read all information on package and enclosed leaflet
- keep the package. It contains important information.
- store at 20-25°C (68-77°F)
- contains under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 130°F (40°C).

Inactive ingredients: butane, butylated hydroxytoluene, cetyl alcohol, citric acid, dehydrated alcohol, isobutane, isobutyl alcohol, polypropylene glycol, purified water, stearyl alcohol

Questions or comments? 1-800-725-6668

Actual Size

Minoxidil Topical Aerosol, 5% (Foam) is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil Topical Aerosol, 5% (Foam) has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

VERTEX

VERTEX

VERTEX

VERTEX

If men have more hair loss or hair loss in a place different than shown above, Minoxidil Topical Aerosol, 5% (Foam) may not work.

FASTEST RESULTS
USE TWICE DAILY

MADE IN ISRAEL
DIST. BY FROEDER & GAMBLE, CINCINNATI, OH 45202

#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT*

head & shoulders

SCALP X

MINOXIDIL
TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH TREATMENT FOR MEN

CLINICALLY PROVEN TO HELP REGROW HAIR
Revitalizes hair follicles

Easy-to-use foam for men
Three month supply
Unscented

NOT FOR USE BY WOMEN

3 CANS - 2.11 OZ (60 g) EACH

THIS PACKAGE CONTAINS

- 3 60 g (2.11 oz) Cans of Minoxidil Topical Aerosol, 5% (Foam) (Three month supply)
- Information leaflet with complete directions on how to use and obtain best results

USING THE PRODUCT

- To open container: Match arrow on can ring with arrow on cap. Pull off cap.
- Wash the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
- The foam may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam.)
- Hold the can straight upside down and press nozzle to dispense the topical foam product onto your fingers. The total amount of foam applied should not exceed half a capful.
- Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
- After each use, close the container to make child resistant by snapping the cap back on the can.

OPEN CONTAINER

PART THE HAIR

HOLD CAN STRAIGHT UPSIDE DOWN

USE YOUR FINGERS

www.headandshoulders.com
Read the enclosed leaflet for complete directions on how to use and obtain best results.

P&G
www.pg.com

HEAD AND SHOULDERS SCALP X MINOXIDIL HAIR REGROWTH TREATMENT FOR MEN

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-587
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 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTANE (UNII: 6LV4FOR43R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
DEHYDRATED ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-587-01	3 in 1 CARTON	11/01/2021	12/15/2024
1		60 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091344	11/01/2021	12/15/2024

Labeler - The Procter & Gamble Manufacturing Company (004238200)