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 clincial 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 presure. 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

PRINCIPAL DISPLAY PANEL - Carton

Head & Shoulders

SCALP X

MINOXIDIL

TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH

TREATMENT

FOR MEN

CLINICALLY PROVEN TO HELP REGROW HAIR

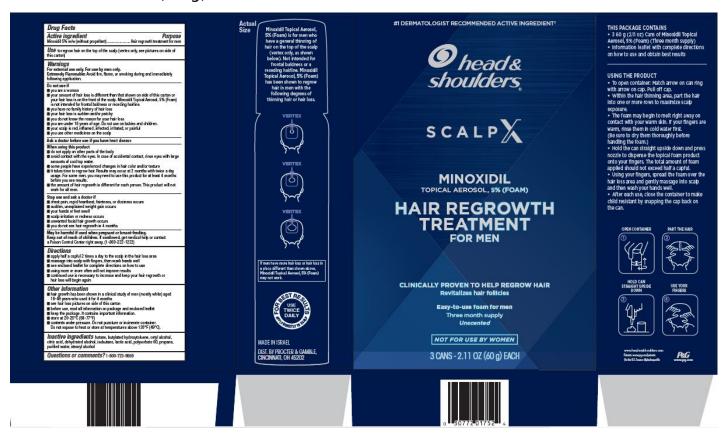
Reactivates hair follicles to stimulate regrowth

Once-a-day foam for women

Six month supply

Unscented

3 CANS - 2.11 OZ (60 g) EACH



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)			

P	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)

Revised: 1/2023