

GROMEDI 5X- minoxidil 5% spray
Orange Lab

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Gromedi 5x Topical Spray

Active Ingredient

**READ AND KEEP PACKAGE AND LEAFLET
FOR FULL PRODUCT INFORMATION.**

ACTIVE INGREDIENT : Minoxidil 5%

WARNINGS:

For external use only.

For use by men and women

Ask a doctor

**Ask a doctor before use if you have
heart disease.**

DO NOT USE IF

Do not use if:

- 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. Gromedi 5X Minoxidil 5% is not intended for frontal baldness or receding hairline.
- You are under 18 years of age.
Do not use on babies and children.
- Your scalp is red, inflamed, irritated or painful.
- You use other medicines on the scalp.

Maybe be harmful if used when pregnant or breast-feeding.

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.

When using this product

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 3 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see the results.
- The amount of hair regrowth is different for each person. This product may not work for all .

Inactive ingredient

Inactive Ingredients :

Aqua/Water, Propylene Glycol, Glycerin, Apigenin, **Biotinoyl Tripeptide-1** , Oleanolic Acid, **Serenoa Serrulata (Saw Palmetto) Fruit Extract**, **Biotin**, Citric Acid, Cetrimonium Bromide, Panthenol, Hydrolyzed Keratin, Calendula Officianalis Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Propolis Extract, Aloe Barbadensis Leaf Extract, Paullinia Cupana (Guarana) Seed Extract, Panax Ginseng Root Extract, Urtica Dioica (Nettle) Extract, PPG-26-Buteth-26, Menthol, Butylene Glycol, PEG-40 Hydrogenated Castor Oil, Tocopheryl Acetate, Benzyl Alcohol, Dehydroacetic Acid, Benzoic Acid, Sea Water Extract, Tetrasodium EDTA.

Directions

Directions :

For Men : Apply 4 to 6 pumps (1ml) 2 times a day directly on the scalp in the hair loss area.

For Women : Apply 4 to 6 pumps (1ml) 1 time a day directly on the scalp in the hair loss area.

Do not use on children

Do not use on babies and children.

- your scalp is red, inflamed, irritated or painful.
- you use other medicines on the scalp.

Directions for dosage / frequency

Directions :

For Men : Apply 4 to 6 pumps (1ml) 2 times a day directly on the scalp in the hair loss area.

For Women : Apply 4 to 6 pumps (1ml) 1 time a day directly on the scalp in the hair loss area.

Dosage and Administration

Directions

For men : Apply 4 to 6 pumps (1ml) 2 times a day directly on the scalp in the hair loss area.

For women : Apply 4 to 6 pumps (1ml) 1 time a day directly on the scalp in the hair loss area.

Using this product :

1. Remove Cap
2. Part the hair
3. Spray on the thinning area
4. Massage with the fingers

Warnings section

Warning : Make sure the liquid does not run down your face. Avoid contact with your eyes. Make sure you wash your hands after use.

Indications and usage

Uses: To regrow hair on the top of the scalp (vertex only, see pictures on side of the carton)

WARNINGS: For external use only.

Minoxidil 5% Topical Spray is for men who have a general thinning hair on the top of the scalp (vertex only, as shown below).

Not intended for frontal baldness or receding hairline. Minoxidil 5% Topical Spray has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN If a child accidentally swallows Gromedi 5x call the toll-free Poison Control Help Line (1-800-222-1222) and seek emergency medical care immediately.

Purpose

Gromedi 5x Topical Spray is for men and women who have a general thinning hair on the top of the scalp.

Not intended for frontal baldness or receding hairline.

Gromedi 5x has been shown to regrow hair in men and women with the thinning hair or hair loss

Front display panel

BIOKEN®

Gromedi 5X

Minoxidil 5%

PLUS BIOTIN & PROCAPIL

Clinically
Proven to help
**Regrow
Hair**

**Hair Growth Treatment
for Men & Women**

**Topical Spray
EXTRA STRENGTH**

4 fl.oz. (118ml)e

GROMEDI 5X

minoxidil 5% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71331-104
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
APIGENIN (UNII: 7V515PI7F6)	
BIOTINOYL TRIPEPTIDE-1 (UNII: O6380721VA)	
SAW PALMETTO (UNII: J7WWH9M8QS)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
URTICA DIOICA ROOT (UNII: J8HE8A6E5T)	
PPG-26-BUTETH-26 (UNII: 2IIIK6TZ4P)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PANTHENOL (UNII: WV9CM0O67Z)	
BIOTIN (UNII: 6SO6U10H04)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BEE PROPOLIS EXTRACT (UNII: 6Y8XYV2NOF)	
PAULLINIA CUPANA SEED (UNII: C21GE7524R)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
MENTHOL (UNII: L7T10EIP3A)	
CETRIMONIUM BROMIDE (UNII: L64N7M9BWR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71331-104-04	118 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/23/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/22/2018	

Labeler - Orange Lab (004862271)

Registrant - Orange Lab (004862271)

Establishment

Name	Address	ID/FEI	Business Operations
Orange Lab		004862271	manufacture(71331-104)

Revised: 10/2018

Orange Lab