

5% MINOXIDIL SPRAY.- 5% minoxidil spray spray
Consilii LLC

83299-028

Active Ingredient

Minoxidil 5%

Purpose

Hair Regrowth Treatment

Use

to regrow hair on the top of the scalp

Warnings

For external use only

Keep away from fire and flame

Avoid contact with eyes

Do not use

You have no family history of hair loss, hair loss is sudden and/or patchy
you are under 18 years of age. Do not use it on babies and children

When Using

Do not apply on other parts of the body

avoid contact with eyes. In case of accidental contact, rinse eyes with a large amount of cool tap water

It takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results, The amount of hair regrowth is different for each person

Stop Use

chest pain, rapid heart beat, faintness, or dizziness occurs

sudden, unexplained weight gain occurs

your hands or feet swell

scalp irritation or redness occurs

Ask Doctor

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 1ml(5 Sprays) twice a day. Once in the morning and another time in the evening before bed

Spray directly on top of the scalp in the area to be treated

Discontinuing use may result in hair loss

Other information

Before use, read all information on the carton

Store at controlled room temperature 20 to 25 C (68 to 77°F)

Inactive ingredients

Deionized Water, Propylene Glycol, Ethyl Alcohol, Potassium Sorbate, GABA

Questions

Tomumcs@gmail.com

PRINCIPAL DISPLAY PANEL

Size / Package size: 4.4*4.4*15.2cm

Bottle label size: 11.6*8.4cm



5% MINOXIDIL SPRAY.

5% minoxidil spray spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83299-028
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
ALCOHOL (UNII: 3K9958V90M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
.GAMMA.-AMINOBTYRIC ACID (UNII: 2ACZ6IPC6I)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83299-028-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	10/07/2023	

Labeler - Consilii LLC (118891890)

Establishment

Name	Address	ID/FEI	Business Operations
Consilii LLC		118891890	label(83299-028) , manufacture(83299-028)

Revised: 5/2024

Consilii LLC