

5% MINOXIDIL FOAM- 5% minoxidil foam spray, suspension
Consilii LLC

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 do not know the reason for your hair loss

you are under 18 years of age. Do not use it on babies and children

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 half a capful 2 times a day directly to the scalp in the hair loss area

Massage into scalp with fingers, then wash well

Using more than directed or more often will not improve results.

Continued use is necessary to increase and then maintain your hair regrowth

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

contact@sunyoobeauty.com

PRINCIPAL DISPLAY PANEL



5% MINOXIDIL FOAM

5% minoxidil foam spray, suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83299-016
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
ALCOHOL (UNII: 3K9958V90M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.GAMMA.-AMINOBTYRIC ACID (UNII: 2ACZ6IPC6I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83299-016-01	60 g in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2023	
2	NDC:83299-016-02	60 g in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075357	10/08/2023	

Labeler - Consilii LLC (118891890)

Establishment			
Name	Address	ID/FEI	Business Operations
Consilii LLC		118891890	label(83299-016) , manufacture(83299-016)

Revised: 10/2023

Consilii LLC