## SUAVECITO 5% MINOXIDIL SOLUTION- minoxidil liquid SUAVECITO, INC.

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#### **SUAVECITO 5% Minoxidil Solution**

#### **Drug Facts**

#### **Active Ingredient**

Minoxidil 5% w/v

#### **Purpose**

Hair Regrowth Treatment For Men

#### Use

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

#### Warnings

#### For external use only. For use by men only

Flammable: Keep away from fire or flame

#### Do not use if

- you are a women
- your amount of hair loss is different than that shown on the side of this carton
- your hair loss is on the front of the scalp. Minoxidil Topical Solution 5% 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

#### 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
- 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.

#### **Directions**

- apply one mL with dropper 2 times a daydirectly onto the scalp in the hair loss area
- using more or more often will no improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

#### Other information

- Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)
- see hair loss pictures on side of this carton
- before use, read all information on carton and enclosed leaflet
- keep the carton. It contains important information
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% Minoxidil Topical Solution for men
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% Minoxidil Topical Solution for men provided more hair regrowth than 2% Minoxidil Topical Solution

#### Inactive Ingredients

Alcohol, Propylene Glycol, Purified Water

#### **Ouestions or comments?**

call toll-free phone number (714) 388-6920 or reach us online at website www.suavecto.com

#### Package Labeling:1 COUNT



Package Labeling:3 COUNT



#### **SUAVECITO 5% MINOXIDIL SOLUTION**

minoxidil liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74866-414

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)
MINOXIDIL
50 mg in 1 mL

# Inactive Ingredients Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0K00R)

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1	NDC:74866-414- 01	1 in 1 BOX	07/31/2023					

1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:74866-414- 03	3 in 1 BOX	07/31/2023	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing I	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA076239	07/31/2023			

### Labeler - SUAVECITO, INC. (078681797)

Revised: 7/2023 SUAVECITO, INC.