

ANTISEPTIC FORMULA FILLED SWAB - lidocaine hydrochloride, benzalkonium chloride liquid
Swabplus Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Antiseptic Formula Filled Swab

Active ingredients

Benzalkonium Chloride 0.11%

Lidocaine Hydrochloride 1.0%

Purpose

Benzalkonium Chloride for Antiseptic

Lidocaine Hydrochloride for Pain relief

Uses

Uses First aid to help prevent infection, and temporarily relieve pain and itching associated with minor cuts, scrapes and burns.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Hold the swan vertically, with the color tip upwards. Hold in the center of the tube with one hand and at the color ring with the other.
- Gently snap the tip with the color ring. Formula inside the tube flows down and fills the opposite tip.
- Apply the product to the affected area.
- Discard swab after use.

Warnings

- **For external use only.** Keep out of eyes and ear canal. Non-Sterile. Discontinue use if irritation occurs.
- **Do not use.** longer than one week unless directed by a doctor.
- **Stop use and ask a doctor if** you have deep or puncture wounds, or serious burns, redness, irritation, swelling or pain continues or increase, infection occurs.

Administration

- **For adult and children 2 and older:**Clean affected area and apply 1 to 3 times daily. May be covered with a bandage.
- **Children under 2 years of age:** Do not use, consult a doctor.

Other information

Store at room temperature. Avoid direct sunlight, excessive heat and moisture.

Inactive ingredients

Dizolidinyl Urea, Methylparaben, Propylparaben, water.

Patent

Patented and manufactured by Swabplus Inc. Rancho Cucamonga, CA 91730 Made in USA

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Package and Label

Image of antiseptic carton label



ANTISEPTIC FORMULA FILLED SWAB

lidocaine hydrochloride, benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65734-270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	100 mg in 10 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	11 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white (Colorless)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65734-270-72	72 in 1 PACKET		
1	NDC:65734-270-00	0.15 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2003	

Labeler - Swabplus Inc. (876441549)

Registrant - Swabplus Inc (876441549)

Establishment

Name	Address	ID/FEI	Business Operations
Swabplus Inc		876441549	manufacture(65734-270) , relabel(65734-270) , repack(65734-270)

