

EASY TO BREAK-OFF CLEANING AND DISINFECTING SWABSTICK DFB-I- isopropyl alcohol swab

Longood Medicine (Beijing) Co., Ltd.

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.

Drug Fact

Active Ingredient

Isopropyl Alcohol 70%

Chlorhexidine Gluconate 2%

Direction:

- Clean the affected area
- Apply the product to the area 1-3 times daily and discard.
- Maybe covered with a sterile bandage when dry

Purpose

Antiseptic

Use

First aid to help prevent infection in minor cuts, scrapes, and burns

Warning

For external use only.

Do Not Use

- use in the eyes
- apply over large areas of the body
- use on individuals who are allergic or sensitive to iodine

Stop Use and Consult a Doctor

- if the condition persists or gets worse
- for use longer than 1 week. Ask a doctor in case of deep or puncture wounds, animal bites, serious burns

Ask a doctor in case of deep or puncture wounds, animal bites, serious burns

Keep out of reach of children

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

Inactive Ingredient

Chlorhexidine Glutamate, Nonoxynol-10, Purified water

Image of Pouch Label

NDC: 62382-0322-x	
Easy to break-off cleaning and disinfecting	
swabstick	
REF:XBT-I	
% Chlorhexidine gluconate(CHG) and Isopropyl alcohol(IPA)	
Sterile	
Manufactured by Longood Medicine (Beijing) Co., Ltd. No.13, Yunteng Road, Miyun Economic Development Zone, Miyun County Beijing P.R. 101500 China	Lot No.: Exp: Vol:
Drug Facts	
Active ingredient Isopropyl alcohol (70%)	Purpose Antiseptic
Patient preoperative Skin preparation <i>Use First aid to help prevent infection in minor cuts, scrapes, and burns</i>	
Warnings For external use only. Do not • use in the eyes • apply over large areas of the body • use on individuals who are allergic or sensitive to Chlorhexidine gluconate (CHG) and isopropyl alcohol (IPA) Stop use and consult a doctor • if the condition persists or gets worse • for use longer than 1 week.	
Ask a doctor in case of deep or puncture wounds, animal bites, serious burns Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Clean the affected area • Apply product on the area 1-3 time daily and discard • May be covered with a sterile bandage when dry	
Inactive Ingredients chlorhexidine gluconate(2%) Nonoxynol-10, purified water	

EASY TO BREAK-OFF CLEANING AND DISINFECTING SWABSTICK DFB-I

isopropyl alcohol swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62382-0323
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-10 (UNII: K7O76887AP)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:62382-0323-1	0.2 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:62382-0323-2	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:62382-0323-3	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:62382-0323-4	0.5 mL in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:62382-0323-5	0.6 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/28/2015	

Labeler - Longood Medicine (Beijing) Co., Ltd. (529553064)

Establishment

Name	Address	ID/FEI	Business Operations
Longood Medicine (Beijing) Co., Ltd.		529553064	manufacture(62382-0323)

Revised: 4/2015

Longood Medicine (Beijing) Co., Ltd.