CHLORA-CLEANZE- chlorhexidine gluconate and isopropyl alcohol swab
Biotronix Healthcare Industries, 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.

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purposes
Antiseptic

Warnings
For external use only. Flammable keep away from fire or flame.

- do not use with electrocautery procedures

Do not use

- On patients with allergies to Chlorhexidine gluconate or Isopropyl alcohol
- As a general skin cleanser or on open wounds

Stop use immediately if irritation or allergic reaction occurs. Contact your doctor immediately!

Directions

- The maximum treatment area is 2.5” x 2.5”
- Point directional arrow downward
- Hold applicator at both ends firmly and with a flexible firm motion break center seal at perforations.
- Remove side of applicator case with applicator tip and discard other side according to institutional

procedures.

- Apply solution to site using lateral stokes in both directions. (30 seconds for dry sites and 2

minutes for moist sites)

- Allow area to dry sufficiently. Dry sites for 30 seconds and moist areas for 1 minute.
- Single use only. Discard remaining solution. Entire solution is not required to be used

Inactive ingredients USP purified water

Use prior to surgery to prepare patient’s skin. Helps in the reduction of potentially harmful bacteria which can cause skin infections.

Other information
■ store between 15–30 °C (59–86 °F)
■ avoid freezing and excessive heat above 40 °C (104 °F)

Keep out of reach of children contact Poison Control or get medical help immediately.

Biotronix Healthcare®

NDC # XXXXXXXXX

3ml CLEAR

CHLORA-CLEANZE

Proprep-I Applicators

2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)
Patient Pre-OP Skin Preparation
Packaging is sterile if unopened or undamaged.
Non-sterile solution

Drug Facts

Active ingredients	Purposes
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

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Warnings

For external use only, Flammable keep away from fire or flame.

- do not use with electrocautery procedures

Do not use

- On patients with allergies to Chlorhexidine gluconate or Isopropyl alcohol.
- As a general skin cleanser or on open wounds

Stop use immediately if irritation or allergic reaction occurs. Contact your doctor immediately!

Keep out of reach of children contact Poison Control or get medical help immediately.

Drug Facts (continued)

Directions

- The maximum treatment area is 4" x 5"
- Point directional arrow downward
- Hold applicator at both ends firmly and with a flexible firm motion break center seal at perforations.
- Remove side of applicator case with applicator tip and discard other side according to institutional procedures.
- Apply solution to site using lateral stokes in both directions. (30 seconds for dry sites and 2
- minutes for moist sites)
- Allow area to dry sufficiently. Dry sites for 30 seconds and moist areas for 1 minute.
- Single use only. Discard remaining solution. Entire solution is not required to be used

Other information

- store between 15–30 °C (59–86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

USP purified water

Questions? ■ www.biotronixhealthcare.com
■ (M-F 8 a.m.–5 p.m. CST) ■ call 1-305-749-9970

SEE REVERSE SIDE FOR MORE INFORMATION

NDC # XXXXXXXXX

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Non-sterile solution

REF# OR71005
See Drug Facts and Label information

WARNING
FLAMMABLE
KEEP AWAY FROM FIRE OR FLAME

STERILE R

External Use Only
Professional Use Only

Manufactured for:
Biotronix Healthcare Industries Inc.
Margate, Florida, 33186
Made in China

CHLORA-CLEANZE

chlorhexidine gluconate and isopropyl alcohol swab

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71389-001
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
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71389-001-04	3 mL in 1 POUCH; Type 0: Not a Combination Product	04/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	04/18/2017	

Labeler - Biotronix Healthcare Industries, Inc. (065762392)

Registrant - US MED PHARM SUPPLIES, INC. (831533109)

Establishment

Name	Address	ID/FEI	Business Operations
Longood Medicine (Beijing) Co., Ltd.		529553064	manufacture(71389-001)

Revised: 7/2017 Biotronix Healthcare Industries, Inc.