CHLORHEXIDINE GLUCONATE APPLICATOR- chlorhexidine gluconate applicator solution
Miraclean Technology Co.,Ltd
Reference Label Set Id: 9ee5676c-3661-44e1-e053-2995a90a9214

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% solution
Isopropyl alcohol, 70% solution

ask a doctor

If any irritation or allergic reaction occurs

Do not use

■ If any open wounds
■ If package damaged or expired
■ If the patient is allergic to chlorhexidine gluconate or any other ingredient in this product

Keep out of the reach of children

Keep out of the reach of children

Purpose

Antiseptic

Stop use and ask a doctor

If any irritation or allergic reaction occurs

Inactive ingredient

■ Water

Other information

■ Stored between 4-30
Avoid exclusive heat above 40 (104° F)

Directions

Peel apart the package and remove the applicator
Pull and remove the ring collar lock from the handle
Wet the treatment area with the fluid
Press down the handle to activate and release the solution flow into the sponge pad

Use

For skin preparation before surgery

Warnings

■ Single-use product
■ Keep away from flames or sparks
■ Keep out of the reach of children

LABEL

CHLORHEXIDINE GLUCONATE APPLICATOR

chlorhexidine gluconate applicator solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73565-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 g in 100 g
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	2 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73565-011-26	26 g in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/17/2020	
2	NDC:73565-011-10	10.5 g in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/17/2020	

Labeler - Miraclean Technology Co.,Ltd (529423940)

Establishment

Name	Address	ID/FEI	Business Operations
Miraclean Technology Co.,Ltd		529423940	manufacture(73565-011)

Revised: 2/2020 Miraclean Technology Co.,Ltd