CHLORAPREP ONE-STEP- chlorhexidine gluconate and isopropyl alcohol solution
CareFusion 213 LLC

ChloraPrep® 0.67ml Sepp® Applicator

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purposes

Antiseptic

Antiseptic

Use

for the preparation of the patient's skin prior to surgery or injection. Helps to reduce bacteria that potentially can cause skin infection.

Warnings

For external use only

Flammable, keep away from fire or flame.

- do not use with electrocautery procedures

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children.

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

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 cm^2)
- remove applicator from package; do not touch applicator tip
- hold the sponge tip down and pinch the barrel of the applicator only once to activate the ampule and release the antiseptic
- wet the sponge tip by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- completely wet the treatment area with antiseptic
- **dry surgical sites** (e.g., abdomen or arm): use gentle repeated back-and-forth strokes for approximately 30 seconds. Allow the area to air dry for approximately 30 seconds.
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for approximately 2 minutes. Allow the area to air dry for approximately 1 minute.
- do not blot or wipe away
- discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

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.chloraprep.com
- call **1-800-523-0502** (M-F 8 a.m.-5 p.m. CST)

Package/Label Principal Display Panel

PRINCIPAL DISPLAY PANEL-CARTON

0.67ml

SEPP ®

APPLICATORS

Clear

Do Not Reuse

Not made with natural rubber latex

STERILE EO

200 applicators

0.02 fl. oz. (0.67 ml) each

NDC 054365-400-03

Cat. No.260449

ChloraPrep ® One-Step

2% w/v chlorhexidine gluconate (CHG)

and 70% v/v isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

Professional Use Only

Store between 15-30 °C (59-86 °F)

Avoid freezing and excessive heat above 40 °C (104 °F)

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54365-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-03	200 in 1 CARTON	10/07/2002	
1		1 in 1 POUCH		
1		0.67 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021555	10/07/2002	

Labeler - CareFusion 213 LLC (826496312)

Registrant - CareFusion 213 LLC (831684456)

Establishment

Name	Address	ID/FEI	Business Operations
CareFusion 213 LLC		826496312	analysis(54365-400) , manufacture(54365-400) , label(54365-400) , pack(54365-400)

Revised: 6/2021 CareFusion 213 LLC