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

BD ChloraPrep™ Clear 10.5 mL Applicator with Sterile Solution

WARNING. FLAMMABLE.

Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- solution contains alcohol and gives off flammable vapors
- avoid getting solution into hairy areas. Hair may take up to 1 hour to dry.
 Wet hair is flammable.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area

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. Helps to reduce bacteria that potentially can cause skin infection.

Warnings

For external use only. Flammable, keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY:

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- do not allow solution to pool

• remove wet materials from prep area

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 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.
- use in a well ventilated area.
- maximal treatment area for one applicator is approximately 8.4 in. x 8.4 in. (457 cm²)
- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Pinch wings **only once** to activate the ampule and release the antiseptic.
- wet the sponge 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 surgicalsites** (e.g., abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth

- strokes for 2 minutes
- do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). 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)

USP purified water

Questions?

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

Principal Display Panel-Carton BD ChloraPrep™ Clear 10.5 mL Applicator with Sterile Solution



Principal Display Panel-Carton

BD ChloraPrep™ Clear

10.5 mL Applicators

2% w/v chlorhexidine gluconate (CHG)

and 70% v/v Isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

Sterile Solution

Applicator is sterile if package is intact

Store between 15-30 °C (59-86 °F)

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

0.36 fl. oz. (10.5 mL) each

25 Applicators

Clear

NDC 54365-400-34

REF 930700

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- do not allow solution to pool
- remove wet materials from prep area

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	
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				
77	Item Code	Package Description Marketing Start Date		Marketing End Date
	C:54365- 0-34	25 in 1 CARTON	05/24/2019	
1		1 in 1 POUCH		
1		10.5 mL in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
1				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA020832	05/24/2019		

Labeler - CareFusion 213, LLC (826496312)

Registrant - Becton, Dickinson and Company (832696038)

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

Revised: 7/2025 CareFusion 213, LLC