

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

Chloraprep Clear 26 mL Applicator

WARNING
FLAMMABLE

Keep away from fire or flame.

To reduce the risk of fire, PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery or on an area

smaller than **8.4 in. x 8.4 in.** Use a smaller applicator instead.

- 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:

- do not use 26-ml applicator for head and neck surgery
- do not use on an area smaller than **8.4 in. x 8.4 in.** Use a smaller applicator instead.
- 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

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 **13.2 in. x 13.2 in. (1126 cm²)**. Do not use 26-ml applicator for area smaller than **8.4 in. x 8.4 in.** Use a smaller applicator instead. • do not use 26-ml applicator for head and neck surgery • remove applicator from package; do not touch sponge • hold the applicator with the sponge down. Pinch wing **only once** to activate the ampules 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 surgical sites** (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)

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

REF 930800
NDC 54365-400-37

 **BD Chloraprep™ Clear**
26 mL Applicator
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

Clear

⚠ WARNING

WARNING
FLAMMABLE



Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery or on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- 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

Drug Facts

Active Ingredients

Chlorhexidine gluconate 2% w/v..... Antiseptic
Isopropyl alcohol 70% v/v..... Antiseptic

Purposes

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:

- do not use 26-ml applicator for head and neck surgery
- do not use on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- 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

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 13.2 in. x 13.2 in. (1126 cm²). Do not use 26-ml applicator for area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- do not use 26-ml applicator for head and neck surgery
- remove applicator from package; do not touch sponge
- hold the applicator with the sponge down. Pinch wing **only once** to activate the ampules 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 surgical sites** (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)

Inactive ingredient USP purified water

Questions?

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

CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co.
Artwork No. 6-930840 • A050619 • Made in the USA of US and imported parts • www.bd.com

External Use Only
Professional Use Only



STERILE EO



Package Label-

BD Chloraprep Clear

26 mL Applicator

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

Clear

REF 930800

NDC 54365-400-37

External Use Only

Professional Use Only

STERILE EO

STERILE SOLUTION

CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co.

Made in the USA of US and imported parts www.bd.com

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:54365-400	
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: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-37	1 in 1 POUCH	05/24/2019	
1		26 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	NDA020832	05/24/2019		

Labeler - CareFusion 213, LLC (826496312)

Registrant - CareFusion 2200, Inc (832696038)

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