

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

BD Chloraprep™ Hi-Lite Orange™ 3 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 the 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

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 **4 in. x 5 in. (130 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 surgical sites** (e.g., abdomen or arm): use gentle repeated back-and-forth strokes of the sponge for approximately 30 seconds. Allow solution to air dry for approximately 30 seconds. Do not blot or wipe away.
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes of the sponge for approximately 2 minutes. Allow solution to air dry for approximately 1 minute. Do not blot or wipe away.
- **If using an ignition source, 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

FD&C yellow #6 dye, USP purified water

Questions?

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

BD ChloroPrep™ Hi-Lite Orange™ 3 mL Applicator with Sterile Solution Principal Display Panel-Package Label

Principal Display Panel-Package Label

BD ChloroPrep™ Hi-Lite Orange™

3 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

NDC 54365-400-33

REF 930415

BD ChloroPrep™ Hi-Lite Orange™

3 mL Applicator

REF 930415 NDC 54365-400-33

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

External Use Only
Professional Use Only



Hi-Lite Orange™

STERILE EO



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

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:

- 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 **4 in. x 5 in. (130 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 surgical sites** (e.g., abdomen or arm): use gentle repeated back-and-forth strokes of the sponge for approximately 30 seconds. Allow solution to air dry for approximately 30 seconds. Do not blot or wipe away. • **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes of the sponge for approximately 2 minutes. Allow solution to air dry for approximately 1 minute. Do not blot or wipe away. • **if using an ignition source, 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) • the tint will slowly fade from the skin. Soap and water, or alcohol may be used to remove the tint if desired.

Inactive ingredients FD&C yellow #6 dye, 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. 6-930421 • A050619 • Made in the USA of US and imported parts • www.bd.com

BD ChloroPrep™ Hi-Lite Orange™ 3 mL Applicator with Sterile Solution Principal Display Panel-Carton Label

Principal Display Panel-Carton

BD ChloroPrep™ Hi-Lite Orange™

3 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

25 Applicators

NDC 54365-400-33

REF 930415

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	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-33	25 in 1 CARTON	05/24/2019	
1		1 in 1 POUCH		
1		3 mL in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
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 Compay (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: 11/2025

CareFusion 213, LLC