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

ChloraPrep® Hi-Lite Orange® 26ml Applicator

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME

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. × 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

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

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.

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flame. To reduce the risk of fire, PREP CAREFULLY:

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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.

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.
- remove applicator from package; do not touch sponge
- hold 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

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)

Package/Label Principal Display Panel

Single Use

ChloraPrep® With Tint

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

26 ml APPLICATOR

Hi-Lite Orange®

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Drug Facts

Active ingredients	Purposes
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

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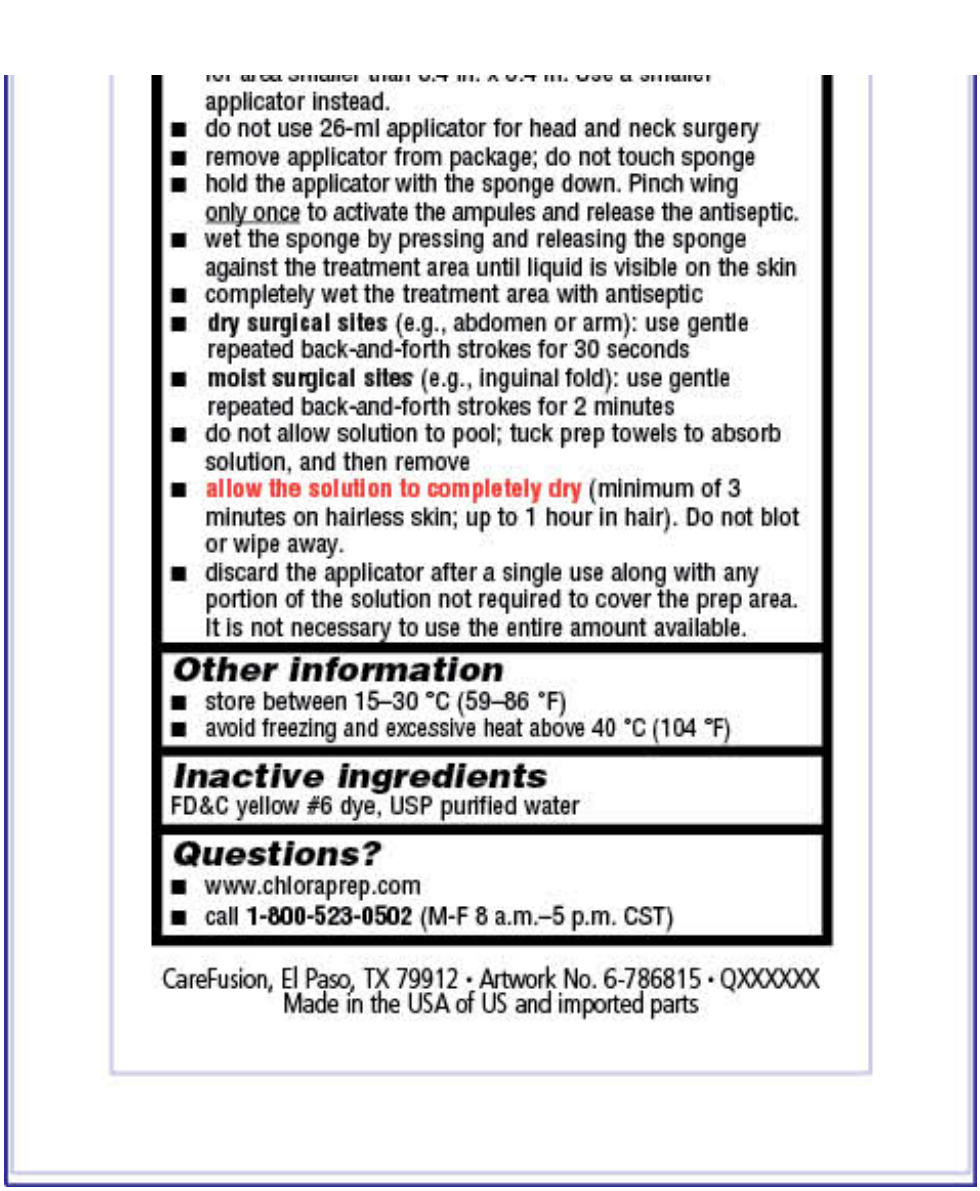
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- **allow the solution to completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
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Other information
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Inactive ingredients
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Made in the USA of US and imported parts

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)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-13	1 in 1 POUCH	08/18/2006	
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	08/18/2006	

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)

Revised: 9/2017 CareFusion 213 LLC