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

ChloraPrep® 3ml Hi-Lite Orange®

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

Do not use

- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- 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 cm^2)
- 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 for 30 seconds
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- **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.

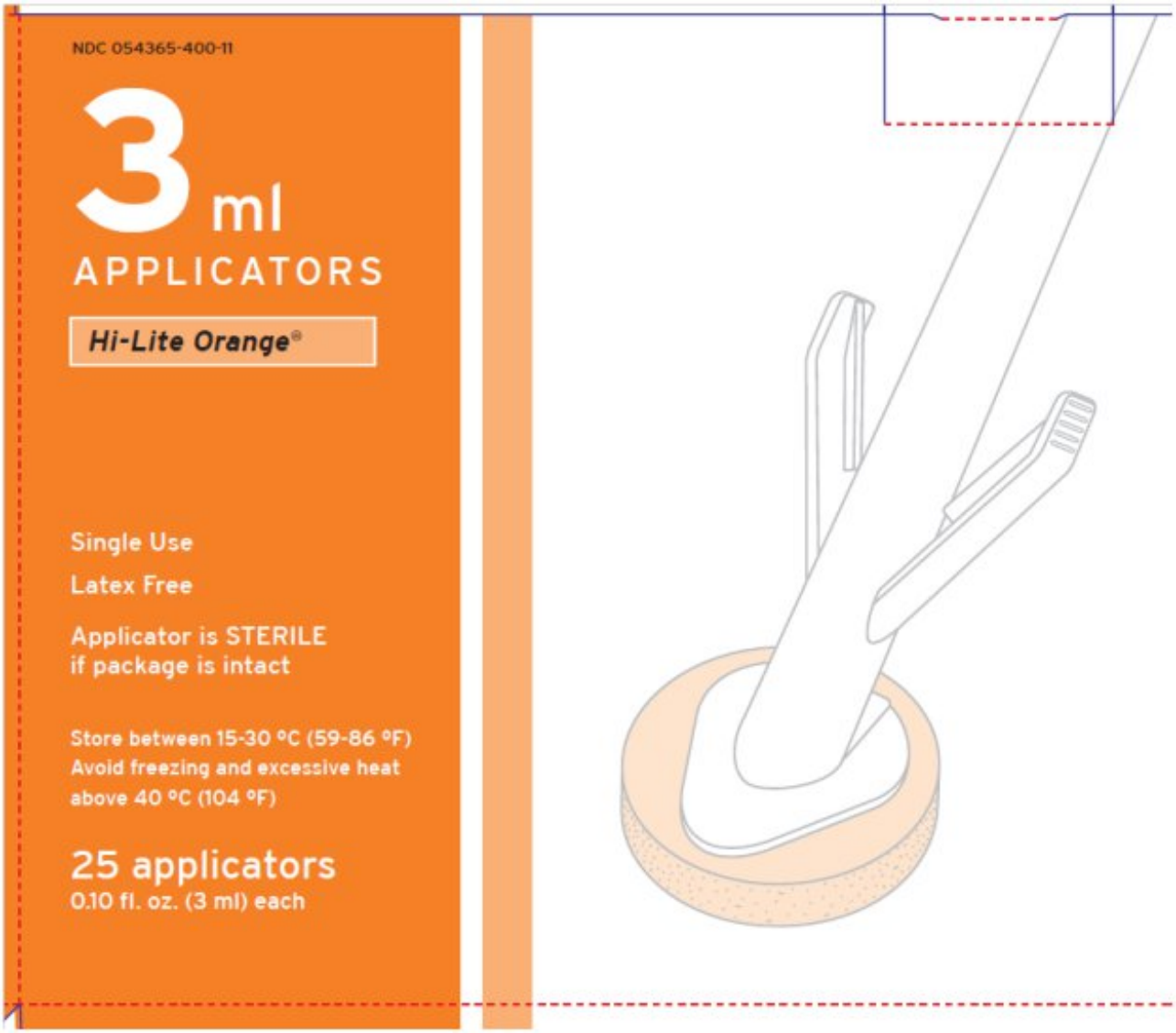
Inactive ingredients

- 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)

Package/Label Principal Display Panel



3ml Hi-Lite Orange Carton Primary Display Panel

NDC 054365-400-11

3ml APPLICATORS

Hi-Lite Orange®

Single Use

Latex Free

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)

25 applicators

0.10 fl. oz. (3 ml) each

CHLORAPREP ONE-STEP

chlorhexidine gluconate and isopropyl aclohol solution

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:54365-400
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (CHLORHEXIDINE)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL
ISOPROPYL ALCOHOL (ISOPROPYL ALCOHOL)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	
FD&C YELLOW NO. 6	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-11	25 in 1 CARTON		
1		1 in 1 POUCH		
1		3 mL in 1 APPLICATOR		

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 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: 12/2012 CareFusion 213 LLC