CHLORAPREP ONE-STEP- chlorhexidine gluconate and isopropyl alcohol solution CareFusion 213 LLC Reference Label Set Id: 8f37915a-292d-4f7b-881a-211d9d032c7e Reference Label Set Id: 000506eb-0340-4d15-9dd1-71f10c83a3b9

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ChloraPrep® 26mL Non-Sterile Solution Applicators, Clear, Hi-Lite Orange, Scrub Teal

#### 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

#### 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:

- 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 meningea
- 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 cm  $^2$ ). 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 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 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)

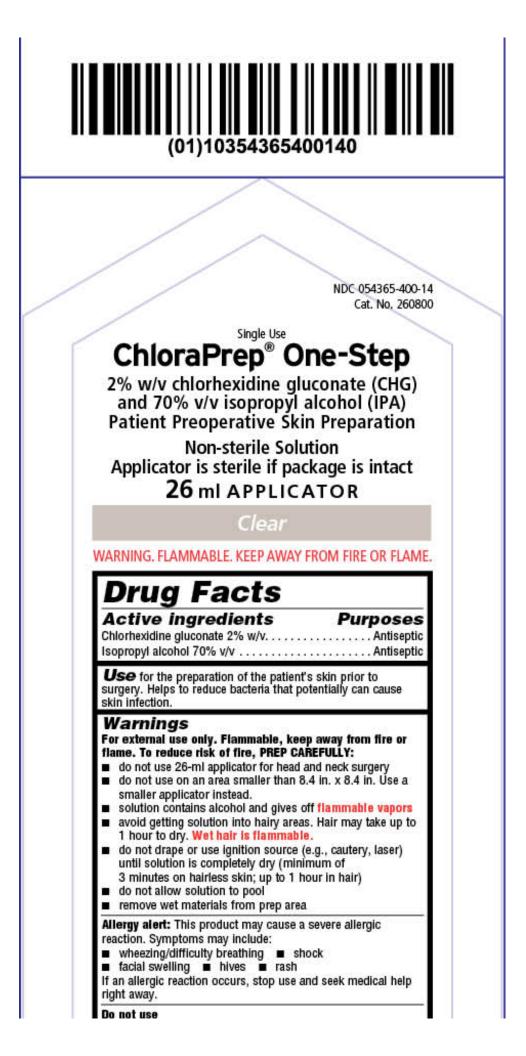
## Inactive ingredient

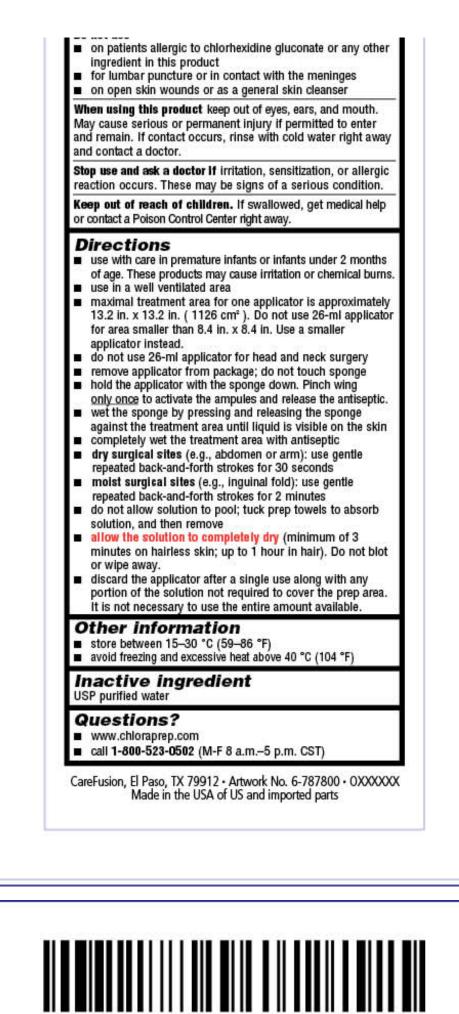
USP purified water

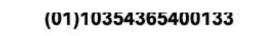
## Questions?

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

# Package Label: 26mL Applicators Non-Sterile Solution: Clear, Hi-Lite Orange, Scrub Teal







NDC 054365-400-13 Cat. No. 260815

Purposes

# 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

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Hi-Lite Orange\*

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

# **Drug Facts**

#### Active ingredients

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

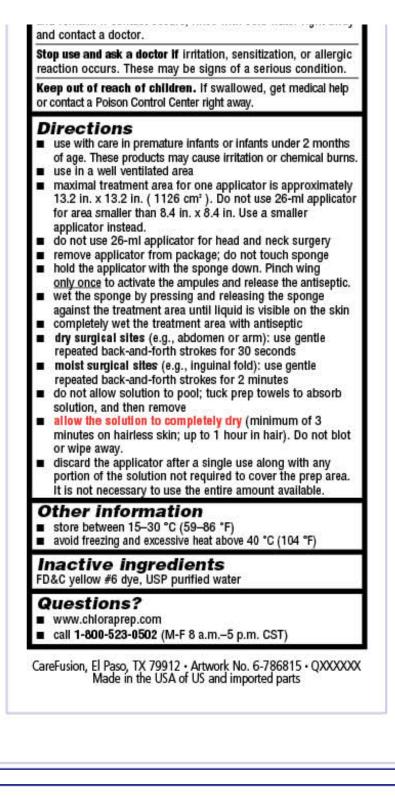
- wheezing/difficulty breathing shock
- facial swelling in hives in rash

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





NDC 054365-400-05 Cat. No. 260825

# 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 mI APPLICATOR

# Scrub Teal\*

WARNING, FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

# Drug Facts

Active ingredients

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 in hives in 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.



#### **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	<b>Basis of Strength</b>	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4K00DY52L)	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)									
P	ackaging								
#	ltem Code	Package Description			Market Start Da		Marketing End Date		
1	NDC:54365- 400-14	1 in 1 POUCH		07/14/2000					
1				Type 9: Other Ty ce/Biological Prod		ombination			
2	NDC:54365- 400-13	1 in 1 POUCH				08/18/2006	5		
2		26 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)							
3	NDC:54365- 400-05	1 in 1 POUCH 04/26/20			04/26/2002				
3		26 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)							
Marketing Information									
Marketing Category			Application	Number or Mo Citation	nograph	Marketir Da	-	Ma	rketing End Date
NDA			NDA020832			07/14/2000			

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) , manufacture(54365-400) , label(54365-400) , pack(54365-400) , sterilize(54365-400)

Revised: 11/2023

CareFusion 213 LLC