

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

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. 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 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**
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- 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 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 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



(01)10354365400140

NDC 054365-400-14
Cat. No. 260800

Single Use

ChloroPrep® One-Step

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

Clear

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

Drug Facts

Active ingredients	Purposes
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 ■ 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, El Paso, TX 79912 • Artwork No. 6-787800 • OXXXXXX
Made in the USA of US and imported parts



(01)10354365400133

NDC 054365-400-13
Cat. No. 260815

Single Use

ChloroPrep[®] 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**

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

Drug Facts

Active ingredients

Purposes

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.**
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- 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

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and contact a doctor.

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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
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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.
- 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)

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(01)10354365400058

NDC 054365-400-05
Cat. No. 260825

Single Use

ChloroPrep[®] 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

Scrub Teal[®]

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

Drug Facts

Active ingredients	Purposes
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

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- hives
- rash

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- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
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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.
- 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 green #3 dye, USP purified water

Questions?

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

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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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54365-400-14	1 in 1 POUCH	07/14/2000	
1		26 mL in 1 APPLICATOR; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:54365-400-13	1 in 1 POUCH	08/18/2006	
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	04/26/2002	
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 Monograph Citation	Marketing Start Date	Marketing 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