

FINAL RELEASE APPROVAL

Artwork No. 6-824480
HXXXXXX

NDC 054365-400-06



BD ChloraPrep™ Clear
1 mL Applicators
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

Store between 15-30 °C (59-86 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)

0.03 fl. oz (1 mL) each
60 Applicators

BD ChloraPrep™ Clear
1 mL Applicators
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

60 Applicators

NON-VARNISH AREA
LOT & EXP PRINTED IN-LINE
DOES NOT PRINT

BARCODE PLACEHOLDER

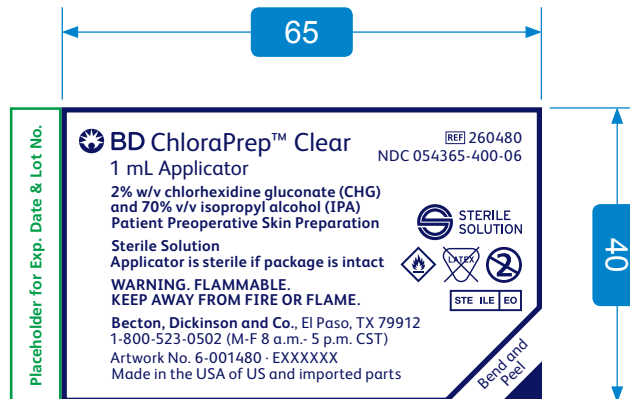
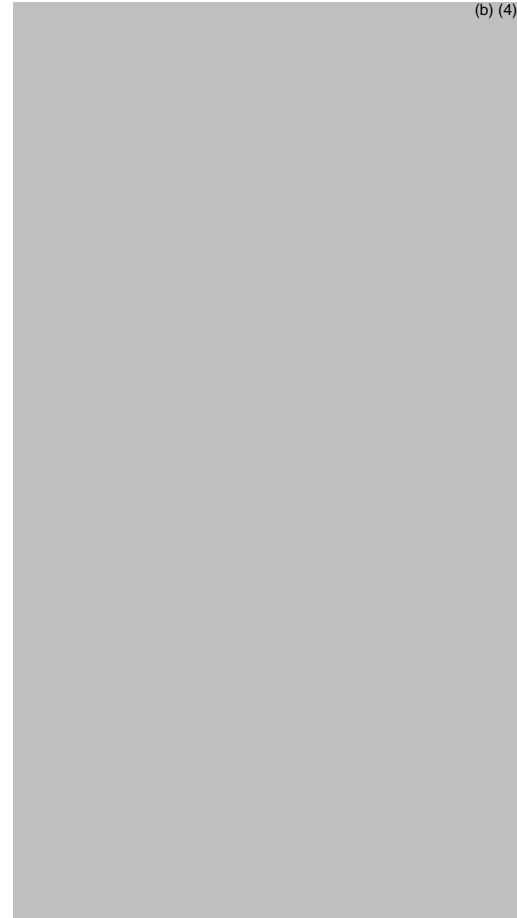
BD ChloraPrep™ Clear

| Drug Facts | |
|--|--|
| Active ingredients: Chlorhexidine gluconate 2% w/v Isopropyl alcohol 70% v/v | Purposes: Antiseptic Antibiotic |
| 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. Do not use with electrocautery procedures. Caution: 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: • in patients allergic to chlorhexidine gluconate or any other ingredients 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. • Maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (6.25 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 30 seconds. Allow the area to air dry for approximately 30 seconds. • Moist surgical sites (e.g., inguinal fold); use gentle repeated back and forth strokes of the sponge for 2 minutes. Allow the area to air dry for approximately 1 minute. • Do not lick 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.bd.com • call 1-800-523-0502 (M-F 8 a.m.-5 p.m. CST) | |

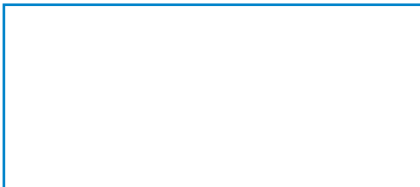


External Use Only
Professional Use Only

BD



FINAL RELEASE APPROVAL



4.75

3.8

BD Chloraprep™ Clear REF 260480 / 260480NSB
NDC 054365-400-06

1 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

External Use Only
Professional Use Only

STERILE SOLUTION

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.

- do not use with electrocautery procedures

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.

FRONT

BD Chloraprep™ Clear

1 mL Applicator

2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)

Drug Facts (continued)

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.
- maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 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 for approximately 30 seconds. Allow the area to air dry for approximately 30 seconds.
- **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for approximately 2 minutes. Allow the area to air dry for approximately 1 minute.
- 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)

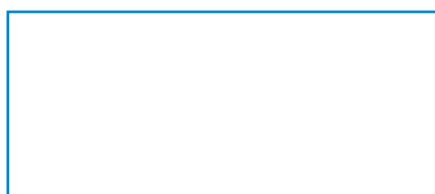
Inactive ingredient USP purified water

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

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REAR

FINAL RELEASE APPROVAL



FINAL RELEASE APPROVAL



Artwork No. 6-824299
WXXXXXX

BD ChloroPrep™ FREPP™ Clear
1.5 mL Applicators

2% w/v chlorhexidine gluconate (CHG)
and 70% v/v isopropyl alcohol (IPA)
Patient Preoperative Skin Preparation

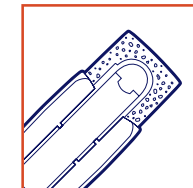
Sterile Solution
Applicator is sterile if package is intact

Store between 15-30 °C (59-86 °F)
Avoid freezing and excessive heat
above 40 °C (104 °F)

0.05 fl. oz (1.5 mL) each
20 Applicators

Clear

NDC 054365-400-02



REF 260299

BD ChloroPrep™ FREPP™ Clear
1.5 mL Applicators
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
20 Applicators

NON-VARNISH AREA
LOT & EXP PRINTED IN-LINE
DOES NOT PRINT

BARCODE PLACEHOLDER

Clear

Drug Facts

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.
• do not use with electrocautery procedures

Allergy alert: This product may cause a severe allergic reaction. Symptoms may include:
• wheezing/difficult 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.

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Drug Facts (continued)

Directions
• use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
• maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 cm²)
• remove applicator from package; do not touch sponge
• hold the applicator horizontally 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. Allow the area to air dry for approximately 30 seconds.
• **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes. Allow the area to air dry for approximately 1 minute.
• 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.chloroprep.com • call 1-800-523-0502 (M-F 8 a.m.–5 p.m. CST)



Not made with natural rubber latex



Do not reuse



STERILE SOLUTION

External Use Only
Professional Use Only

2.484

0.625

8.500

3.500

8.500

3.469

24.594

0.969

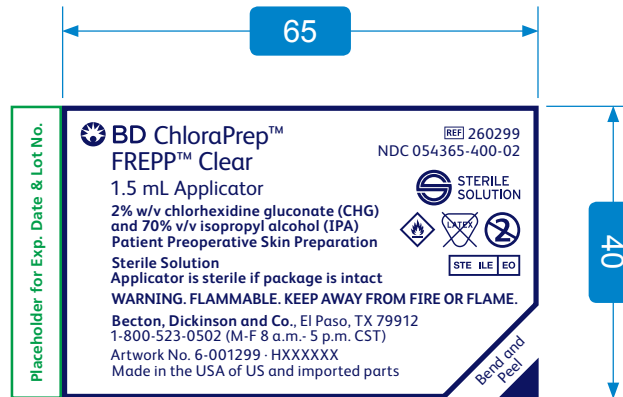
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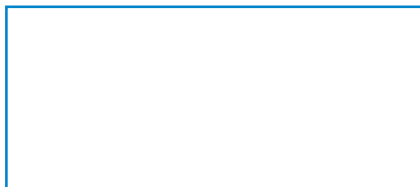
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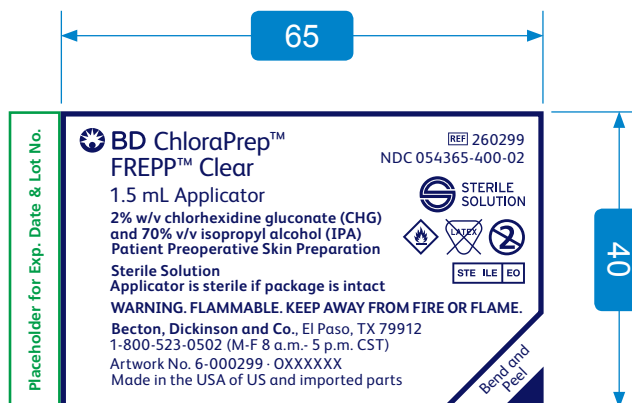
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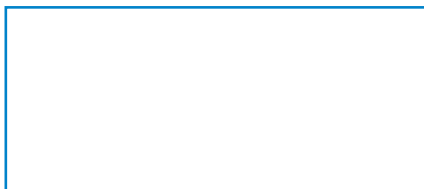


FINAL RELEASE APPROVAL





FINAL RELEASE APPROVAL



2.5

BD ChloraPrep™
FREPP™ Clear
1.5 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

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.
• do not use with electrocautery procedures

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.
• maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 cm²)
• remove applicator from package; do not touch sponge
• hold the applicator horizontally 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 approximately 30 seconds. Allow the area to air dry for approximately 30 seconds.
• **moist surgical sites** (e.g., inguinal fold): use gentle repeated back-and-forth strokes for approximately 2 minutes. Allow the area to air dry for approximately 1 minute.
• 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)

See other side for additional information


7.5


FRONT

REF 260299NSB / 260599NSB
NDC 054365-400-02

BD ChloraPrep™
FREPP™ Clear
1.5 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

See Drug Facts for Full Labeling Information

 Flammable

 Not made with natural rubber latex

 Do not reuse

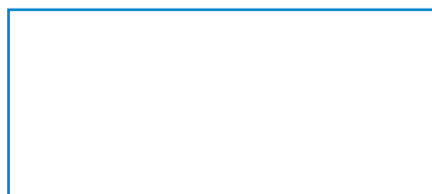
 **STERILE SOLUTION**

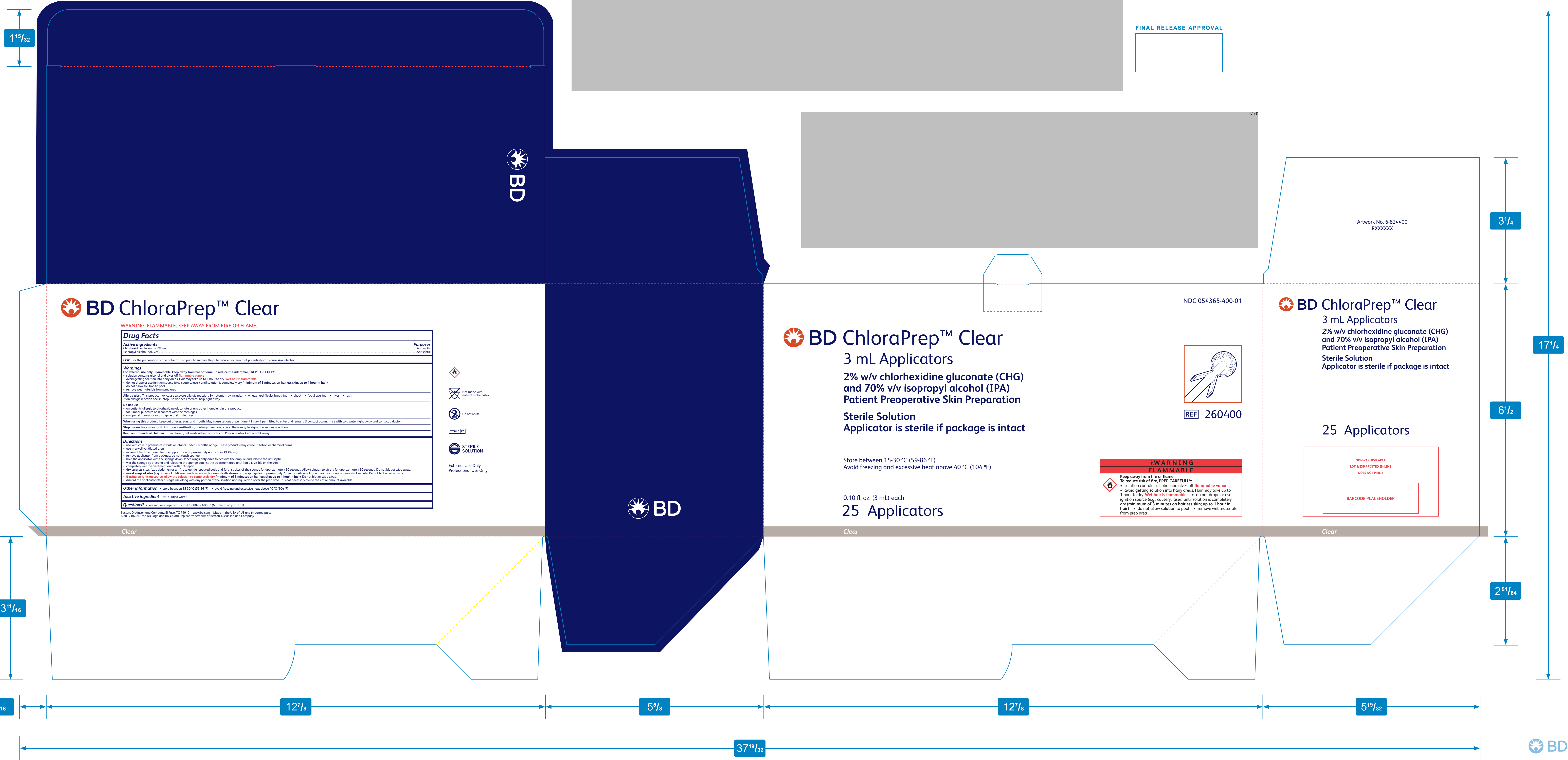
External Use Only
Professional Use Only

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SXXXXXX
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REAR

FINAL RELEASE APPROVAL





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FINAL RELEASE APPROVAL

Artwork No. 6-824400
RXXXXXX

3 1/4

BD ChloraPrep™ Clear

WARNING, FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

| Drug Facts | Purposes |
|--|--------------------------|
| Active Ingredients Chlorhexidine gluconate 2% w/v Isopropyl alcohol 70% v/v | 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 cautery 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 keratin puncture or in contact with the neovagina • 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, soreness, or allergic reaction occurs. There 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 on 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) • 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 weight 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 weight 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. Do 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.bdchlorep.com • call 1-800-523-6502 (M-F 8 a.m.-5 p.m. CST) | |
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Do not use

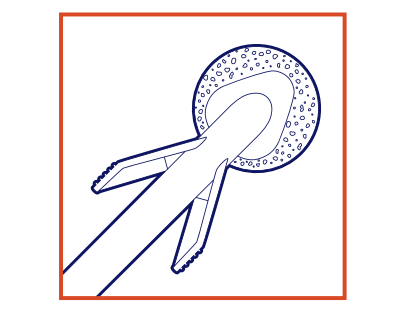
STERILE SOLUTION

External Use Only
Professional Use Only

BD ChloraPrep™ Clear

3 mL Applicators
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 054365-400-01



REF 260400

Store between 15-30 °C (59-86 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)

0.10 fl. oz. (3 mL) each
25 Applicators

**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

BD ChloraPrep™ Clear
3 mL Applicators
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

NON-WARNING AREA
LOT & EXP PRINTED IN-LINE
DOES NOT PRINT
BARCODE PLACEHOLDER

17 1/4

6 1/2

2 51/64

1 1/16

12 7/8

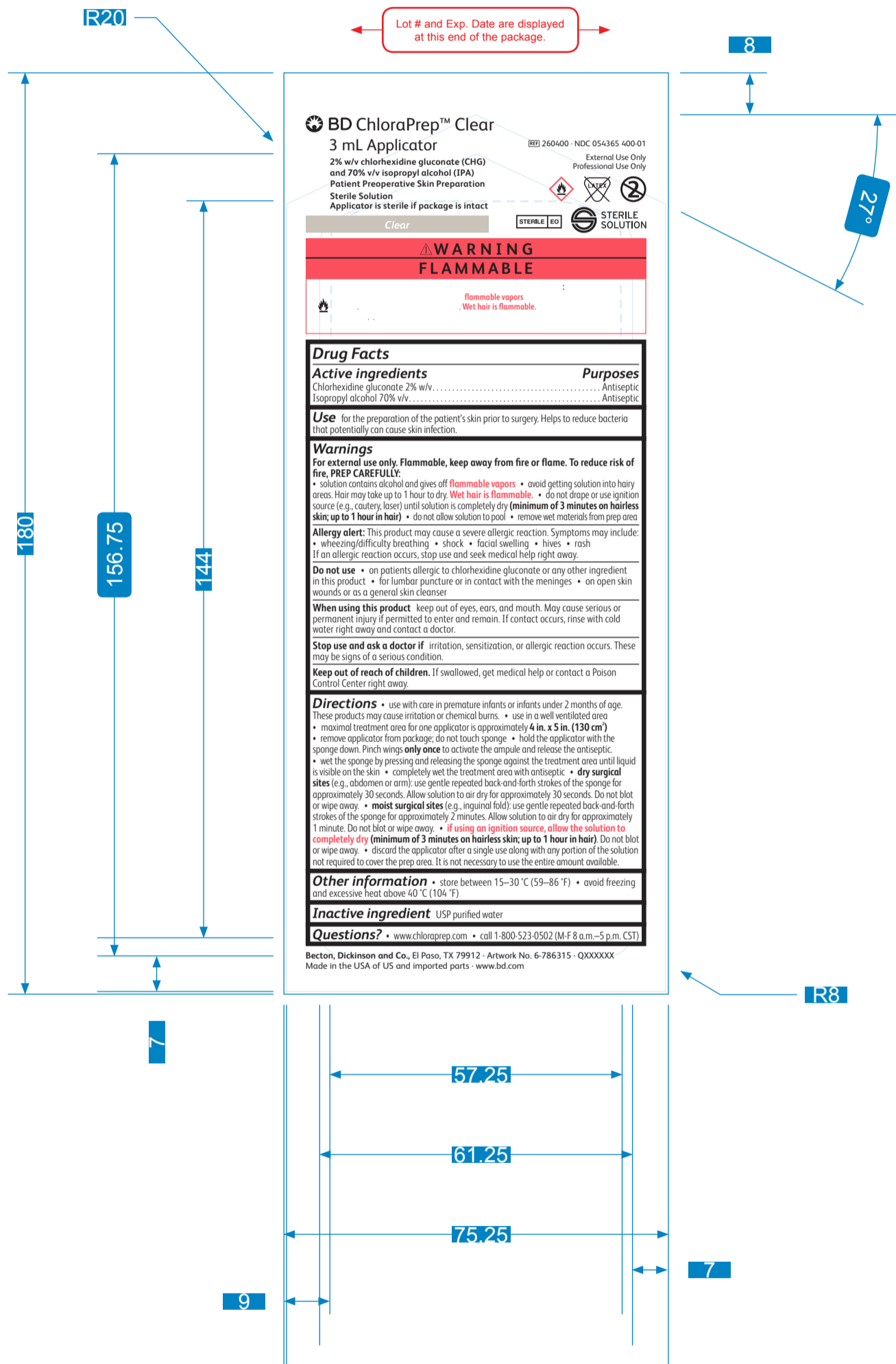
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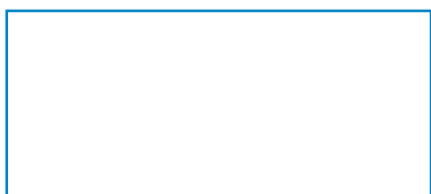
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FINAL RELEASE APPROVAL



4.75

**⚠ 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

NDC 054365-400-01
NDC 054365-400-11

BD ChloraPrep™ Clear
BD ChloraPrep™ 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

STERILE SOLUTION External Use Only
Professional Use Only

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:

- 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.

FRONT

BD ChloraPrep™ Clear / BD ChloraPrep™ Hi-Lite Orange™
2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)

Drug Facts (continued)

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.

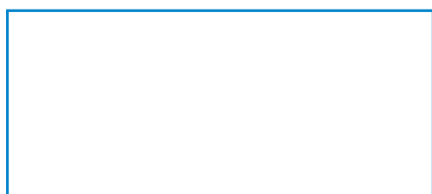
Inactive ingredients FD&C yellow #6 dye (Hi-Lite Orange applicators only), USP purified water

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

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REAR

FINAL RELEASE APPROVAL



This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
04/03/2019 12:00:00 AM