



Attachment # 1: NDA 19-127 -Revised labeling, BD E-Z Scrub 32-ounce Round

<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <p>• use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</p> <p><b>Surgical hand scrub:</b></p> <ul style="list-style-type: none"> <li>• wet hands and forearms with water</li> <li>• scrub for 3 minutes with about 2.0 cubic inches of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces</li> <li>• a separate nail cleaner may be used • rinse thoroughly</li> <li>• wash for an additional 3 minutes with 2.0 cubic inches of product and rinse under running water • dry thoroughly</li> </ul> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"> <li>• wet hands with water</li> <li>• dispense about 1.5 cubic inches of product into cupped hands, wash in a vigorous manner for 15 seconds, and rinse under running water</li> <li>• dry thoroughly</li> </ul> <p><b>Other information</b> • store at 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F)</p> <p><b>Inactive ingredients</b> cocamide DEA, fragrance, glucono-delta-lactone, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol</p> <p><b>Questions or comments?</b> call 1-800-453-4538 Monday through Friday 8 AM to 5 PM EST</p>	<p>NDC 17271-505-01</p>  <p><b>BD E-Z Scrub™</b></p> <p><b>Chlorhexidine Gluconate 4% Solution Antiseptic</b></p> <p>REF 372402 Foreign Patents and Patents Pending, U.S. Patents 6,053,369 – 6,308,866</p>  <p>010000050024004</p> <p><b>Chlorhexidine Gluconate</b></p> <p>32 fl oz (946 mL)</p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purposes</th> </tr> </thead> <tbody> <tr> <td>Chlorhexidine gluconate 4% solution</td> <td>surgical hand scrub healthcare personnel handwash</td> </tr> </tbody> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• <b>surgical hand scrub:</b> significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li> <li>• <b>healthcare personnel handwash:</b> helps reduce bacteria that potentially can cause disease</li> </ul> <p><b>Warnings</b> For external use only</p> <p><b>Allergy alert:</b> This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• wheezing/difficulty breathing</li> <li>• shock</li> <li>• facial swelling</li> <li>• hives</li> <li>• rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• if you are allergic to chlorhexidine gluconate or any other ingredient in this product</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.</li> <li>• if solution should contact these areas, rinse out promptly and thoroughly with water</li> <li>• do not use routinely if you have wounds which involve more than the superficial layers of the skin</li> </ul> <p><b>Stop use and ask a doctor if</b> irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredient	Purposes	Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash
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Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash					

**To install:** 1. Remove bottle cap and apply dispensing cap. Slide dispenser into bracket, inserting the open air inlet onto proper receptacle.  
**Container is single use only. Discard when empty.**  
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 Manufactured for: Becton, Dickinson and Company, Franklin Lakes NJ 07417, Made in USA.

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Attachment # 2: NDA 19-127 -Revised labeling, BD E-Z Scrub 32-ounce Square

**Drug Facts (continued)**

- a separate nail cleaner may be used • rinse thoroughly
- wash for an additional 3 minutes with 2.0 cubic inches of product and rinse under running water
- dry thoroughly

**Healthcare personnel handwash:**

- wet hands with water
- dispense about 1.5 cubic inches of product into cupped hands, wash in a vigorous manner for 15 seconds, and rinse under running water
- dry thoroughly


**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients** cocamide DEA, fragrance, glucono-delta-lactone, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

**Questions or comments?** call 1-800-453-4538 Monday through Friday 8 AM to 5 PM EST

NDC 17271-505-02



**BD E-Z Scrub™**

**Chlorhexidine  
Gluconate 4% Solution  
Antiseptic**

REF 372412  
Foreign Patents and Patents Pending,  
U.S. Patent 6,427,875

**Chlorhexidine Gluconate**

32 fl oz (946 mL)

**Drug Facts (continued)**

**Warnings**  
**For external use only**

**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** • if you are allergic to chlorhexidine gluconate or any other ingredient in this product

**When using this product**

- keep out of eyes, ears and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

**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.

**Surgical hand scrub:**


- wet hands and forearms with water
- scrub for 3 minutes with about 2.0 cubic inches of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces

**Drug Facts**

Active ingredient	Purpose
Chlorhexidine gluconate 4% solution	surgical hand scrub healthcare personnel handwash

**Uses**

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease



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Manufactured for:  
**Becton, Dickinson and Company**, Franklin Lakes NJ 07417,  
Made in USA.

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Dickinson and Company, © 2008 BD.

4BD32SQLBLC

**Drug Facts (continued)**

**Warnings**  
**For external use only**

**Allergy alert:** This product may cause a severe allergic reaction.  
Symptoms may include:

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

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- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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**Directions**

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- wet hands and forearms with water
- scrub for 3 minutes with about 2.0 cubic inches of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces

Reference ID: 4152839

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THERESA M MICHELE  
09/14/2017