



Xitrium Laboratories, Inc. Page 24 of 24  
Chlorhexidine Gluconate 0.75% Solution  
Section 1.14.1-Draft Labeling

Confidential

Attachment # 1 (cont'd): NDA 20-111 -Revised labeling, 4-ounce Dyna-Hex 0.75% CHG

<p><b>Drug Facts</b> (continued)</p> <ul style="list-style-type: none"><li>■ as a surgical hand scrub</li><li>■ on skin wounds</li><li>■ as a general skin cleanser</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 placed or kept in the eye during surgical procedures 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></ul> <p><b>Stop use and ask doctor</b> if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. ▲</p>	<p><b>Drug Facts</b> (continued)</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>■ use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li></ul> <p><b>Healthcare personnel handwash:</b></p> <ul style="list-style-type: none"><li>■ wet hands with water</li><li>■ dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 30 seconds</li><li>■ rinse and dry thoroughly</li></ul> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>■ store at 20-25°C (68-77°F)</li><li>■ avoid excessive heat above 40°C (104°F)</li></ul> <p><b>Inactive Ingredients</b> citric acid, cocamide DEA, FD&amp;C yellow #5, FD&amp;C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol. ▲</p>	<p><b>Drug Facts</b> (continued)</p> <p>lauramine oxide, purified water, ricinobamidopropyl trimethyl ammonium chloride</p> <p><b>Questions or comments? Call 1-773-268-5800</b> Monday through Friday 8:00 AM to 4:30 PM</p>
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Xitrium Laboratories, Inc. Page 24 of 24  
 Chlorhexidine Gluconate 0.75% Solution  
 Section 1.14.1-Draft Labeling

Confidential


Attachment # 2: NDA 20-111 -Revised labeling, 8-ounce Dyna-Hex 0.75% CHG

NDC 0116-1175-08

**DYNA-HEX 0.75<sup>®</sup>**  
 (Chlorhexidine Gluconate 0.75% Solution)  
*Antiseptic*

Contains: 0.75% Chlorhexidine Gluconate  
 Manufactured By: Xitrium Laboratories, Inc.  
 Mount Prospect, IL 60056

**FOR EXTERNAL USE ONLY**



N 0116-1175-08 9

**Net Contents: 8 fl oz (237 ml)**

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**Drug Facts**

<b>Active ingredient</b> chlorhexidine gluconate 0.75% solution .....	<b>Purpose</b> healthcare personnel handwash
<b>Use</b> healthcare personnel handwash: helps reduce bacteria that potentially can cause disease	
<b>Warnings</b> For external use only	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ if you are allergic to chlorhexidine gluconate or any other ingredients</li> <li>■ in contact with meninges</li> <li>■ in the genital area</li> <li>■ as a preoperative skin preparation (especially on the head and face)</li> <li>■ as a surgical hand scrub</li> <li>■ on skin wounds</li> <li>■ as a general skin cleanser</li> </ul>	



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Xtrium Laboratories, Inc.  
Chlorhexidine Gluconate 0.75% Solution  
Section 1.14.1-Draft Labeling

Attachment # 3: NDA 20-111 -Revised labeling, 16-ounce Dyna-Hex 0.75% CHG

NDC 0116-1175-16

**DYNA-HEX 0.75<sup>®</sup>**  
(Chlorhexidine Gluconate 0.75% Solution)  
*Antiseptic*

Net Contents: 16 fl. oz. (473 ml)  
Contains: 0.75% Chlorhexidine Gluconate  
Manufactured By: Xtrium Laboratories, Inc.  
Mount Prospect, IL 60056

**FOR EXTERNAL USE ONLY**



<b>Drug Facts</b>	
<b>Active ingredient</b> chlorhexidine gluconate 0.75% solution	<b>Purpose</b> healthcare personnel handwash
<b>Use</b> healthcare personnel handwash: helps reduce bacteria that potentially can cause disease	
<b>Warnings</b> <b>For external use only</b>	
Do not use <ul style="list-style-type: none"> <li>• if you are allergic to chlorhexidine gluconate or any other ingredients</li> <li>• in contact with meningitis</li> <li>• in the genital area</li> <li>• as a preoperative skin preparation (especially on the head and face)</li> <li>• as a surgical hand scrub</li> <li>• on skin wounds</li> <li>• as a general skin cleanser</li> </ul>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>• keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures 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> </ul>	
Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<b>Directions</b> <ul style="list-style-type: none"> <li>• use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul>	
<b>Healthcare personnel handwash:</b> <ul style="list-style-type: none"> <li>• wet hands with water</li> <li>• dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 30 seconds</li> <li>• dry thoroughly</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>• store at 20-25°C (68-77°F)</li> <li>• avoid excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> citric acid, concamide DEA, FD&C yellow #5, FD&C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, triclosamidopropyl trimethyl ammonium chloride	
<b>Questions or comments?</b> Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM	

Attachment # 4: NDA 20-111 - Revised labeling, 30-ounce Dyna-Hex 0.75% CHG

NDC 0116-1175-30

**DYNA-HEX 0.75<sup>®</sup>**  
(Chlorhexidine Gluconate 0.75% Solution)  
*Antiseptic*

Contains: 0.75% Chlorhexidine Gluconate  
Xttrium Laboratories, Inc.  
Mount Prospect, IL 60056

**FOR EXTERNAL USE ONLY**



Net Contents: 30 fl. oz. (887 ml)

**Drug Facts**

**Active ingredient**  
chlorhexidine gluconate 0.75% solution

**Use**  
healthcare personnel handwash: helps reduce bacteria that potentially can cause disease

**Warnings**  
For external use only

**Do not use** • if you are allergic to chlorhexidine gluconate or any other ingredients • in contact with meningitis • in the genital area  
• as a preoperative skin preparation (especially on the head and face) • as a surgical hand scrub • on skin wounds

**When using this product**  
• keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when inserted in the middle ear through perforated eardrums  
• if solution should contact these areas, rinse out promptly and thoroughly with water

**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.  
**Healthcare personnel handwash:** • wet hands with water  
• dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 30 seconds  
• rinse and dry thoroughly

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

**Inactive ingredients** citric acid, cocamide DEA, FD&C yellow #5, FD&C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, nonoxonyltrimethyl ammonium chloride

**Questions or comments?** Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM CT

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Xttrium Laboratories, Inc.  
Chlorhexidine Gluconate 0.75% Solution  
Section 1.14.1-Draft Labeling

Attachment # 5: NDA 20-111 -Revised labeling, 32-ounce Dyna-Hex 0.75% CHG

NDC 0116-1175-32

**DYNA-HEX 0.75<sup>®</sup>**  
(Chlorhexidine Gluconate 0.75% Solution)  
*Antiseptic*

Contains: 0.75% Chlorhexidine Gluconate  
Manufactured By: Xttrium Laboratories, Inc.  
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY



Net Contents: 32 fl. oz. (1 quart) (946ml)

<b>Drug Facts</b>
<b>Active ingredient</b> chlorhexidine gluconate 0.75% solution
<b>Use</b> healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
<b>Warnings</b> for external use only
<b>Do not use</b> <ul style="list-style-type: none"> <li>if you are allergic to chlorhexidine gluconate or any other ingredients</li> <li>as a preoperative skin preparation (especially on the head and face)</li> <li>as a general skin cleanser</li> </ul>
<b>When using this product</b> <ul style="list-style-type: none"> <li>keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures 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> </ul>
<b>Stop use and ask a doctor if</b> irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> <ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul>
<b>Healthcare personnel handwash:</b> <ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 30 seconds</li> <li>rinse and dry thoroughly</li> </ul>
<b>Other information</b> <ul style="list-style-type: none"> <li>store at 20-25 C (68-77 F)</li> <li>avoid excessive heat above 40°C (104°F)</li> </ul>
<b>Inactive ingredients</b> <ul style="list-style-type: none"> <li>citric acid, cocamide DEA, FD&amp;C yellow #5, FD&amp;C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, rindamidopropyl trimethyl ammonium chloride</li> </ul>
<b>Questions or comments?</b> Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM CT

Attachment # 6: NDA 20-111 -Revised labeling, 1-Gallon Dyna-Hex 0.75% CHG

NDC 0116-1175-33

**DYNA-HEX 0.75<sup>®</sup>**  
(Chlorhexidine Gluconate 0.75% Solution)  
*Antiseptic*

Contains: 0.75% Chlorhexidine Gluconate  
Manufactured By: Xttrium Laboratories, Inc.  
Mount Prospect, IL 60056

**FOR EXTERNAL USE ONLY**



Net Contents: 128 fl. oz. (1 gallon) (3.785 L)

**Drug Facts**

**Active ingredient** chlorhexidine gluconate 0.75% solution,.....healthcare personnel handwash  
**Use** healthcare personnel handwash: helps reduce bacteria that potentially can cause disease  
**Warnings** For external use only

**Drug Facts (continued)**

**Do not use** • if you are allergic to chlorhexidine gluconate or any other ingredients  
• in contact with meningitis  
• in the genital area  
• as a preoperative skin preparation (especially on the head and face)  
• as a surgical hand scrub  
• on skin wounds  
• as a general skin cleanser  
**When using this product**  
• keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures 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  
**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.  
**Healthcare personnel handwash:** • wet hands with water  
• dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 30 seconds  
• rinse and dry thoroughly  
**Other information** • store at 20-25°C (68-77°F)  
• avoid excessive heat above 40°C (104°F)  
**Inactive ingredients** citric acid, cocamide DEA, FD&C yellow #5, FD&C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, triclosan, trimethyl ammonium chloride  
**Questions or comments?** Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM CT

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JOEL SCHIFFENBAUER  
05/08/2013