

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 1: NDA 19-422 -Revised labeling, 4-ounce Dyna-Hex 2% CHG

Label Base

NDC 0116-1021-04

DYNA-HEX 2[®]
(Chlorhexidine Gluconate 2% Solution)
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xitrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY



0 11610 21040 6

Net Contents: 4 fl oz (118 mL)

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 1 (cont'd): NDA 19-422 -Revised labeling, 4-ounce Dyna-Hex 2% CHG

Front Panel (Booklet Front)

NDC 0116-1021-04

DYNA-HEX 2[®]
(Chlorhexidine Gluconate 2% Solution)
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xitrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY


0 11610 21040 6
Net Contents: 4 fl oz (118 mL)

Drug Facts	
Active ingredient	Purpose
chlorhexidine gluconate 2% solution	Antiseptic

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
- **patient preoperative skin preparation:** preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

▲ Lift Here

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 1 (cont'd): NDA 19-422 -Revised labeling, 4-ounce Dyna-Hex 2% CHG

Page 2 (Back of Cover)

<p>Drug Facts (continued)</p>
<p>Warnings For external use only</p>
<p>Do not use</p> <ul style="list-style-type: none">■ if you are allergic to chlorhexidine gluconate or any other ingredients■ in contact with meninges■ in the genital area■ as a preoperative skin preparation of the head or face
<p>When using this product</p> <ul style="list-style-type: none">■ 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■ wounds which involve more than the superficial layers of the skin should not be routinely treated■ repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin
<p>Stop use and ask doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.</p>
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>

Attachment # 1 (cont'd): NDA 19-422 -Revised labeling, 4-ounce Dyna-Hex 2% CHG

Page 3

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.

Surgical hand scrub:

- wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleaning:

- thoroughly rinse the area to be cleaned with water

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

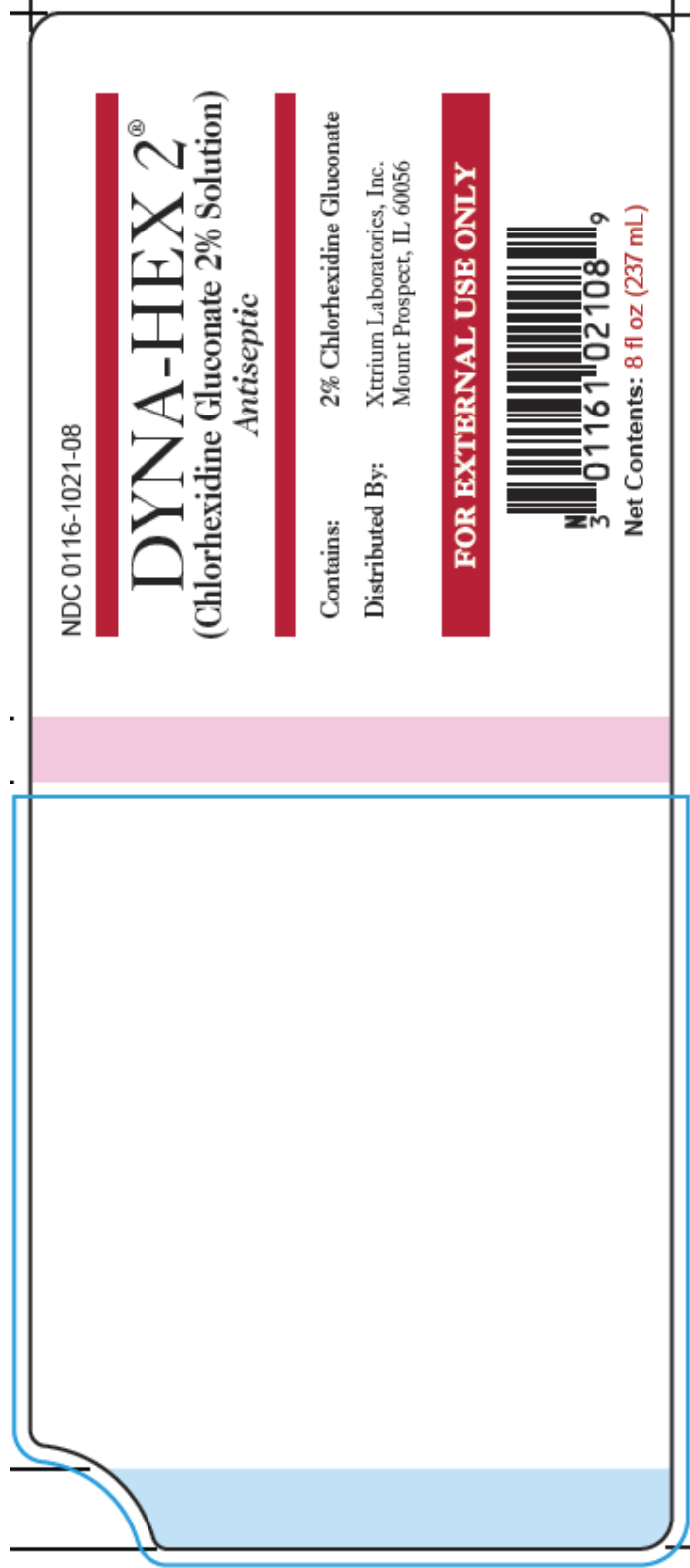
Attachment # 1 (cont'd): NDA 19-422 -Revised labeling, 4-ounce Dyna-Hex 2% CHG

Page 4

Drug Facts (continued) <ul style="list-style-type: none">■ apply the minimum amount of product necessary to cover the skin or wound area and wash gently■ rinse again thoroughly
Other information <ul style="list-style-type: none">■ store at 20-25°C (68-77°F)■ avoid excessive heat above 40°C (104°F)
Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water
Questions or comments? Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM

Attachment # 2: NDA 19-422 -Revised labeling, 8-ounce Dyna-Hex 2% CHG

Label Base



Attachment # 2 (cont'd): NDA 19-422 -Revised labeling, 8-ounce Dyna-Hex 2% CHG


PDP

NDC 0116-1021-08

DYNA-HEX 2[®]
(Chlorhexidine Gluconate 2% Solution)
Antiseptic

Contains: 2% Chlorhexidine Gluconate
Distributed By: Xitrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY


N 0116102108 9
Net Contents: 8 fl oz (237 mL)

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution	Antiseptic

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
- **patient preoperative skin preparation:** preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Warnings
For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area

▲ Lift Here

Xttrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Confidential

Page 11 of 30

Attachment # 2 (cont'd): NDA 19-422 -Revised labeling, 8-ounce Dyna-Hex 2% CHG

Drug Facts (continued)

- as a preoperative skin preparation of the head or face

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
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin

Stop use and ask doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

Keep out 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 under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.
- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 mL of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleaning:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

▼

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

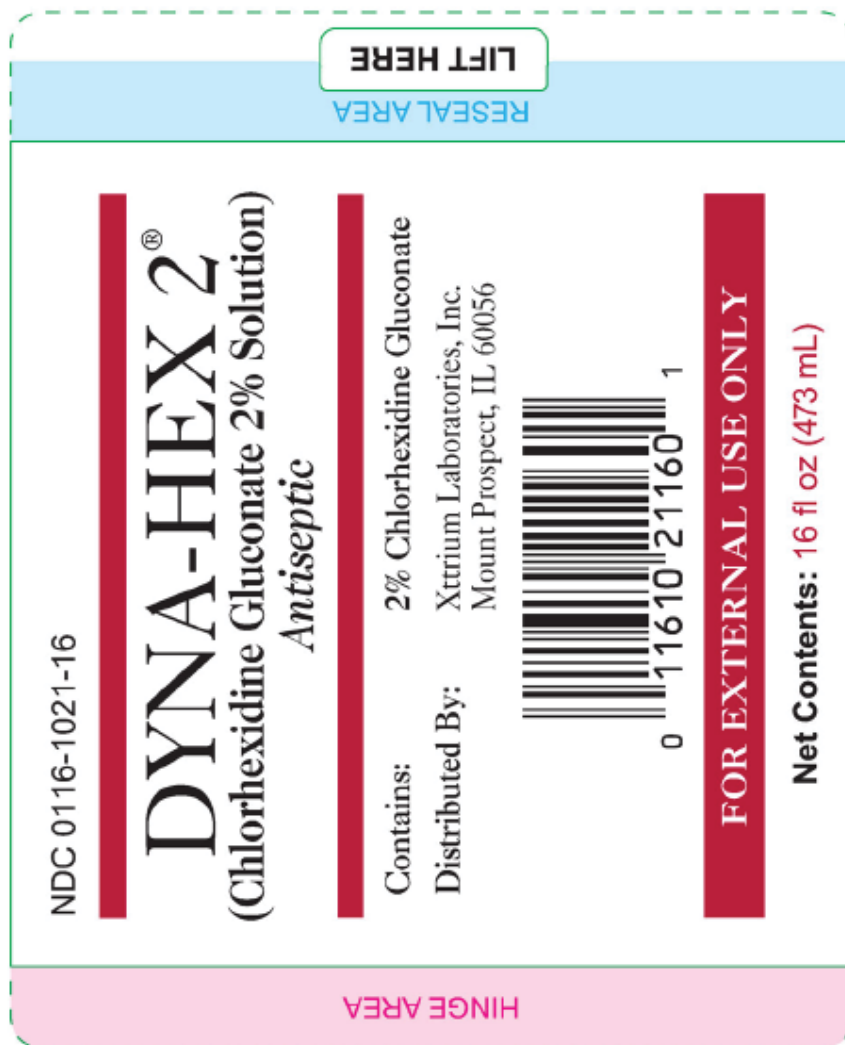
Attachment # 2 (cont'd): NDA 19-422 -Revised labeling, 8-ounce Dyna-Hex 2% CHG

Drug Facts (continued)
Other information <ul style="list-style-type: none">■ store at 20-25°C (68-77°F)■ avoid excessive heat above 40°C (104°F)
Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water
Questions or comments? Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM

2BLDY08BTLBLA

Attachment # 3: NDA 19-422 -Revised labeling, 16-ounce Dyna-Hex 2% CHG

PDP



Attachment # 3 (cont'd): NDA 19-422 -Revised labeling, 16-ounce Dyna-Hex 2% CHG

Panel 2

Drug Facts

Active ingredient chlorhexidine gluconate 2% solution Antiseptic

Purpose Antiseptic

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
- **patient preoperative skin preparation:** preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Warnings

For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

RESEAL AREA

HINGE AREA

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 3 (cont'd): NDA 19-422 -Revised labeling, 16-ounce Dyna-Hex 2% CHG

Panel 3

Drug Facts (continued)

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
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population 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 under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner. ▲

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 3 (cont'd): NDA 19-422-Revised labeling, 16-ounce Dyna-Hex 2% CHG

Panel 4

Drug Facts (continued)

- scrub for 1.5 minutes with about 8 mL of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers.
- rinse thoroughly under running water for 30 seconds
- wash for an additional 1.5 minutes with 8 ml of product and rinse under running water for 30 seconds
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Attachment # 3 (cont'd): NDA 19-422 -Revised labeling, 16-ounce Dyna-Hex 2% CHG

Panel 5

Drug Facts (continued)

Other information

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

Inactive ingredients citric acid, coccamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?
Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

Label Patent #6,413,604

2DYNI6B7LLBL

WS-213

Attachment # 4: NDA 19-422 -Revised labeling, 30-ounce Dyna-Hex 2% CHG

NDC 0116-1021-30

DYNA-HEX 2[®]

Chlorhexidine Gluconate 2% Solution *Antiseptic*

To Install

1. Twist to remove plug from back of dispenser spout.
2. Seat dispenser into bracket, taking care to insert the open air inlet into proper receptacle.
3. Twist to remove plug from end of spout.

Contains: 2% Chlorhexidine Gluconate For External Use Only

Distributed By: Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

Net Contents: 30 fl oz (887 ml)

To Remove

1. Hold bracket against the wall and pull the empty dispenser straight forward.
2. Discard entire bottle and spout.



Attachment # 4 (cont'd): NDA 19-422 -Revised labeling, 30-ounce Dyna-Hex 2% CHG

Drug Facts	Purpose
Active ingredient chlorhexidine gluconate 2% solution	Antiseptic
Uses <ul style="list-style-type: none"> ■ 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 ■ patient preoperative skin preparation: preparation of the patient's skin prior to surgery ■ skin wound and general skin cleansing 	
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 of the head or face 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 ■ wounds which involve more than the superficial layers of the skin should not be routinely treated ■ repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population 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: ■ scrub for 1.5 minutes with about 8 ml of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers ■ rinse thoroughly under running water for 30 seconds ■ wash for an additional 1.5 minutes with 8 ml of product and rinse under running water for 30 seconds ■ dry thoroughly Healthcare personnel handwash: ■ dispense about 5 ml of product into cupped hands and wash in a vigorous manner for about 15 seconds ■ rinse and dry thoroughly Patient preoperative skin preparation: ■ apply product liberally to surgical site and swab for at least 2 minutes ■ repeat procedure for an additional 2 minutes and dry with a sterile towel Skin wound and general skin cleansing: ■ thoroughly rinse the area to be cleaned with water ■ apply the minimum amount of product necessary to cover the skin or wound area and wash gently ■ rinse again 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, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water	
Questions or comments? call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST	

Xttrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 5: NDA 19-422-Revised labeling, 32-ounce Dyna-Hex 2% CHG

Front Panel

NDC 0116-1021-32

DYNA-HEX 2[®]
(Chlorhexidine Gluconate 2% Solution)
Antiseptic



Contains: **2% Chlorhexidine Gluconate**
Distributed By: Xttrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

Net Contents: 32 fl oz (1 qt) (946 ml)

2BLDYN32BTLE

Drug Facts

Active ingredient

chlorhexidine gluconate 2% solution.....Antiseptic

Purpose

Antiseptic

Confidential

Xtrium Laboratories, Inc.
 Chlorhexidine Gluconate 2% Solution
 Section 1.14.1-Draft Labeling

Attachment # 5 (cont'd): NDA 19-422-Revised labeling, 32-ounce Dyna-Hex 2% CHG

Panel 2

<p>Drug Facts (continued)</p> <p>Uses</p> <ul style="list-style-type: none"> • 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 • patient preoperative skin preparation: preparation of the patient's skin prior to surgery • skin wound and general skin cleansing 	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> • use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. <p>Surgical hand scrub:</p> <ul style="list-style-type: none"> • wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner. • scrub for 1.5 minutes with about 8 ml of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers • rinse thoroughly under running water for 30 seconds • wash for an additional 1.5 minutes with 8 ml of product and rinse under running water for 30 seconds • dry thoroughly <p>Healthcare personnel handwash:</p> <ul style="list-style-type: none"> • wet hands with water • dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds • rinse and dry thoroughly <p>Patient preoperative skin preparation:</p> <ul style="list-style-type: none"> • apply product liberally to surgical site and swab for at least 2 minutes • dry with a sterile towel • repeat procedure for an additional 2 minutes and dry with a sterile towel <p>Skin wound and general skin cleansing:</p> <ul style="list-style-type: none"> • thoroughly rinse the area to be cleaned with water • apply the minimum amount of product necessary to cover the skin or wound area and wash gently • rinse again thoroughly
<p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> • if you are allergic to chlorhexidine gluconate or any other ingredients • in contact with meninges • in the genital area • as a preoperative skin preparation of the head or face <p>When using this product</p> <ul style="list-style-type: none"> • keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed 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 • wounds which involve more than the superficial layers of the skin should not be routinely treated • repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin <p>Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Other information</p> <ul style="list-style-type: none"> • store at 20-25 °C (68-77 °F) • avoid excessive heat above 40 °C (104 °F) <p>Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water</p> <p>Questions or comments? Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST</p>

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 6 (cont'd): NDA 19-422-Revised labeling, 1-Gallon Dyna-Hex 2% CHG

Panel 1

Drug Facts (continued)
Warnings For external use only
Do not use <ul style="list-style-type: none">• if you are allergic to chlorhexidine gluconate or any other ingredients• in contact with meninges• in the genital area• as a preoperative skin preparation of the head or face
When using this product <ul style="list-style-type: none">• 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• wounds which involve more than the superficial layers of skin should not be routinely treated• repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population 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. ▲

Attachment # 6 (cont'd): NDA 19-422 -Revised labeling, 1-Gallon Dyna-Hex 2% CHG

Panel 2

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none">• use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. <p>Surgical hand scrub: • wet hands and forearms under running water for 30 seconds. Clean fingernails using a nailstick or similar cleaner.</p> <ul style="list-style-type: none">• scrub for 1.5 minutes with about 8 ml of product with or without a wet brush paying close attention to the nails, cuticles, and skin between the fingers• rinse thoroughly under running water for 30 seconds• wash for an additional 1.5 minutes with 8 ml of product and rinse under running water for 30 seconds• dry thoroughly <p>Healthcare personnel handwash: • wet hands with water</p> <ul style="list-style-type: none">• dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds• rinse and dry thoroughly <p>Patient preoperative skin preparation: • apply product liberally to surgical site and swab for at least 2 minutes</p> <ul style="list-style-type: none">• dry with a sterile towel <ul style="list-style-type: none">• repeat procedure for an additional 2 minutes and dry with a sterile towel <p>Skin wound and general skin cleansing: • thoroughly rinse the area to be cleaned with water</p> <ul style="list-style-type: none">• apply the minimum amount of product necessary to cover the skin or wound area and wash gently• rinse again thoroughly <p>Other information • store at 20-25 °C (68-77 °F)</p> <ul style="list-style-type: none">• avoid excessive heat above 40 °C (104 °F) <p>Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water</p> <p>Questions or comments? Call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM</p>
--

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 7: NDA 19-422-Revised labeling, Bactoshield 1-L 2% CHG



Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 7 (cont'd): NDA 19-422-Revised labeling, Bactosshield 1-L 2% CHG

Drug Facts (continued)
Uses <ul style="list-style-type: none">• 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• patient preoperative skin preparation: preparation of the patient's skin prior to surgery• skin wound and general skin cleansing
Warnings
For external use only
Do not use <ul style="list-style-type: none">• if you are allergic to chlorhexidine gluconate or any other ingredients• in contact with meninges• in the genital area• as a preoperative skin preparation of the head or face
When using this product <ul style="list-style-type: none">• 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 ▲

Confidential

Xitrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Attachment # 7 (cont'd): NDA 19-422-Revised labeling, Bactosshield 1-L 2% CHG

Drug Facts (continued)

- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population 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 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
 - a separate nail cleaner may be used
 - rinse thoroughly
 - wash for an additional 3 minutes with 5 ml of product and rinse under running water
 - dry thoroughly

Attachment # 7 (cont'd): NDA 19-422-Revised labeling, Bactosshield 1-L 2% CHG

Drug Facts (continued)
Healthcare personnel handwash: <ul style="list-style-type: none">wet hands with waterdispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 secondsrinse and dry thoroughly
Patient preoperative skin preparation: <ul style="list-style-type: none">apply product liberally to surgical site and swab for at least 2 minutesdry with a sterile towelrepeat procedure for an additional 2 minutes and dry with a sterile towel
Skin wound and general skin cleansing: <ul style="list-style-type: none">thoroughly rinse the area to be cleaned with waterapply the minimum amount of product necessary to cover the skin or wound area and wash gentlyrinse again thoroughly
Other information <ul style="list-style-type: none">store at 20 - 25°C (68 - 77°F)avoid excessive heat above 40°C (104°F)
Inactive ingredients citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water
Questions or comments? Call 1-800-548-4873 Monday through Friday 8:00 AM to 4:30 PM EST

Confidential

Xitrium Laboratories, Inc.
 Chlorhexidine Gluconate 2% Solution
 Section 1.14.1-Draft Labeling

Attachment # 8: NDA 19-422- Revised Labeling, BD E-Z-Scrub 32-oz 2% CHG

NDC 17271-506-02



BD E-Z Scrub™

Chlorhexidine Gluconate 2% Solution Antiseptic

REF 372416
 Foreign Patents and Patents Pending.
 U.S. Patent 6,427,875

Chlorhexidine Gluconate

32 FL. OZ (946 ml)

Drug Facts (continued)

- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 ml of solution (4 full strokes) and rinse under running water
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense 5 ml of solution (4 full strokes) 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 citric acid, cocamide DEA, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

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

Drug Facts (continued)

Warnings
 For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

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
- wounds that involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population 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 5 ml of solution (4 full strokes) and rinse thoroughly
- pay close attention to the nails, cuticles, and interdigital space

Drug Facts

Active ingredient
 chlorhexidine gluconate 2% solution

Purpose
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

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

BD, BD Logo and BD E-Z Scrub are trademarks of Becton, Dickinson and Company. © 2009 BD. ZBD325QLBLC

Xttrium Laboratories, Inc.
Chlorhexidine Gluconate 2% Solution
Section 1.14.1-Draft Labeling

Confidential

Page 30 of 30

Attachment # 9: NDA 19-422-Revised Labeling, GOJO Provon 1.2 L 2% CHG

PROVON[®]
BRAND

**Antimicrobial
Skin Cleanser**

*Chlorhexidine Gluconate
2% Solution - Antiseptic*

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution	Antiseptic

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

Warnings
For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients

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 ear drums.
- 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.

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles and skin between the fingers
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- rinse and dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- 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, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water

Questions or comments?
call 1-800-321-9647 Monday through Friday
8:30 AM to 5:00 PM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
12/12/2012