

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: Xtrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY


011610210406

Net Contents: 4 fl oz (118 mL)

Front Panel (Booklet Front)

Amendment to NDA 19-422/S-0047-Revision Request

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

Page 2 (Back of Cover)

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 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 of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Drug Facts (continued)

- 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

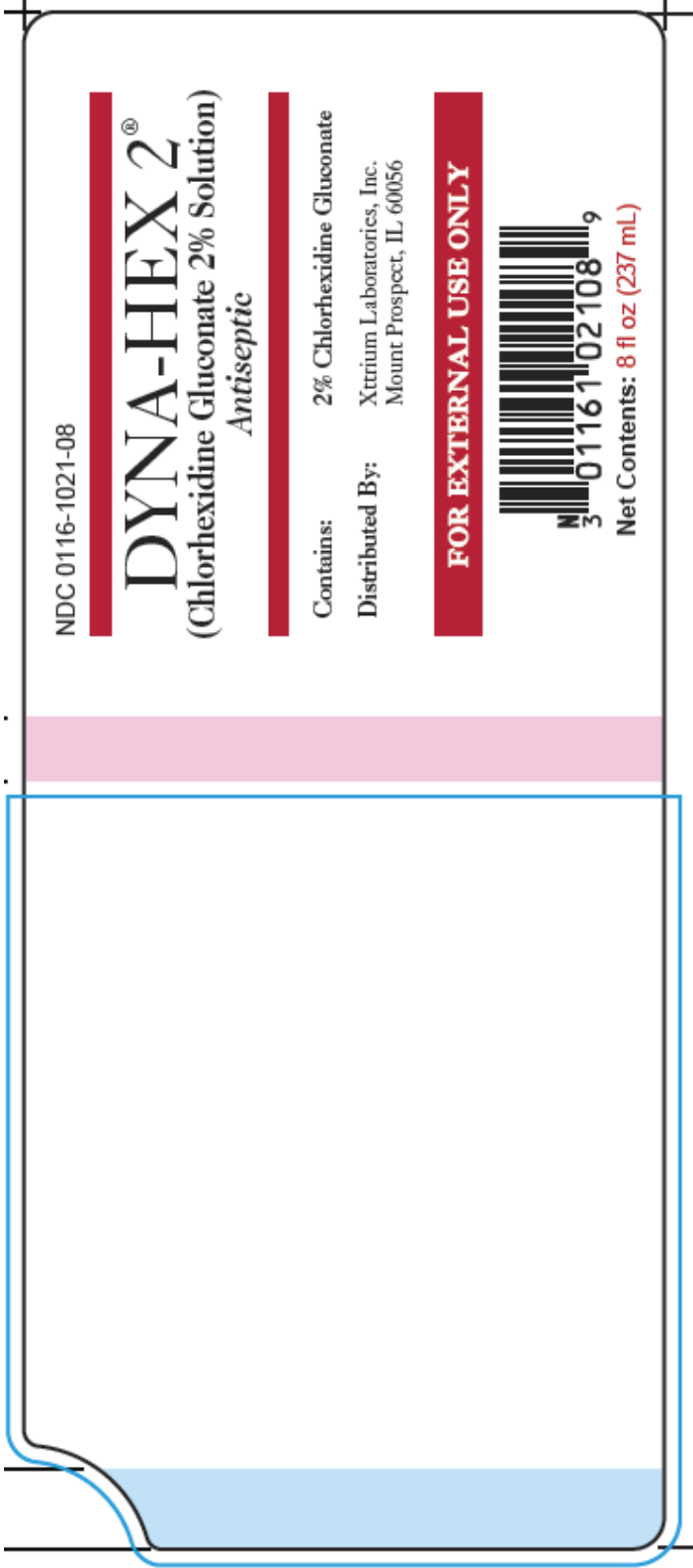
citric acid,
cocamide DEA, hydroxyethylcellulose, isopropyl
alcohol, lauramine oxide, purified water

Questions or comments?

Call 1-800-587-3721
Monday through Friday 8:00 AM to 4:30 PM

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: Xtrium Laboratories, Inc.
Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY


3 01161 02108 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

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

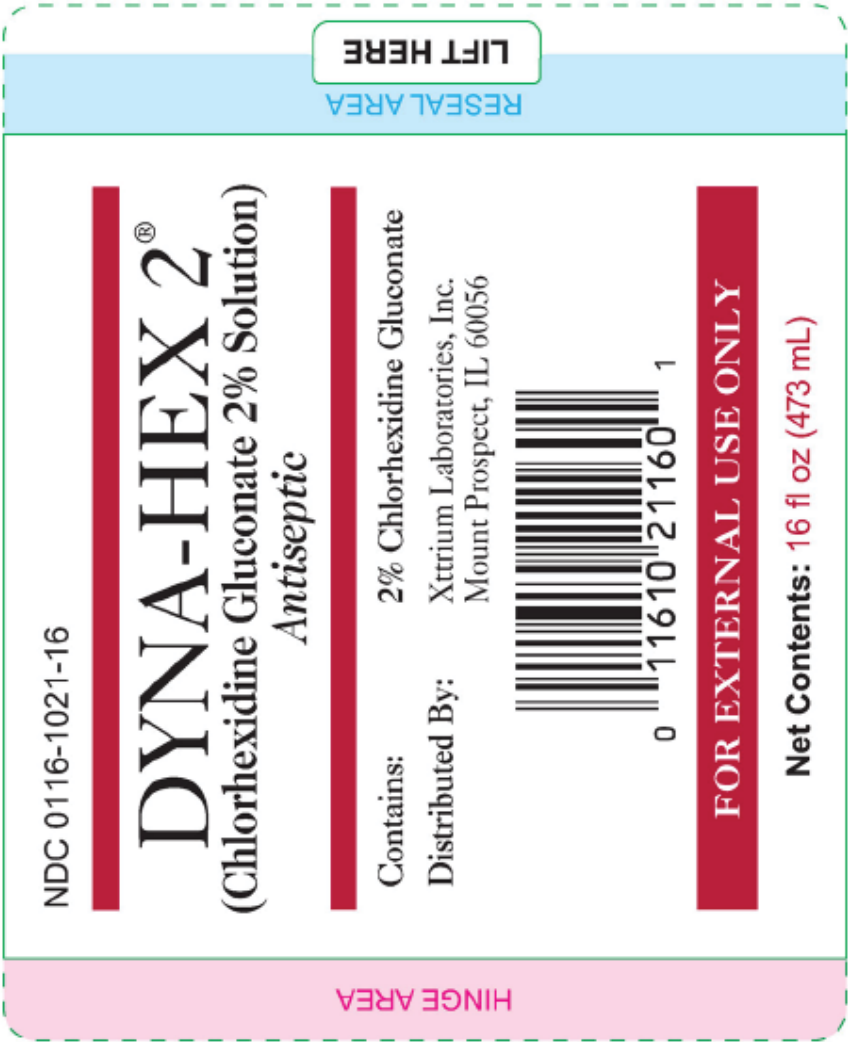
Skin wound and general skin cleaning:

- 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

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

PDP



Panel 2

Amendment to NDA 19-422/S-0047-Revision Request

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.

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

NDC 0116-1021-30



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

To Remove

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

Net Contents: 30 fl oz (887 ml)



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

Drug Facts	
Active ingredient chlorhexidine gluconate 2% solution	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	
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. ■ 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 about 15 seconds ■ rinse and dry thoroughly Patient preoperative skin preparation: ■ apply product liberally to surgical site and swab for at least 2 minutes ■ 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	

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

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FOR EXTERNAL USE ONLY

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

28LDYN32BTLE

Drug Facts

Active ingredient

chlorhexidine gluconate 2% solution

Purpose

Antiseptic

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

Panel 2

Drug Facts (continued)	
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	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 • 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
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 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.	Other information • store at 20-25 °C (68-77 °F) • avoid excessive heat above 40 °C (104 °F)
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	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	

Attachment # 6: NDA 19-422-Revised labeling, 1-Gallon Dyna-Hex 2% CHG

PDP

NDC 0116-1021-01

DYNA-HEX 2[®]

(Chlorhexidine Gluconate 2% Solution)

Antiseptic

Contains: 2% Chlorhexidine Gluconate

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

FOR EXTERNAL USE ONLY

Net Contents: 128 fl oz (1 gal) (3.785 l) 2BLDY1GBTLB

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

Amendment to NDA 19-422/S-0047-Revision Request

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

- 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 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

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

- 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

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

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

NDC 0519-1322-41

BACTOSHIELD® CHG 2%

Chlorhexidine Gluconate 2% Solution
Antiseptic

For Use in SDS Dispenser

1322-87

Net Contents: 33.8 fl oz (1.05 qt) (1 Liter)

Manufactured for STERIS Corporation ■ 7501 Page Avenue ■ St. Louis, MO 63133
800-548-4873 ■ www.steris.com ■ Product Made in U.S.A.

STERIS®





(01)00724995084202

Drug Facts

Active ingredient
chlorhexidine gluconate 2% solution

Purposes
surgical hand scrub
healthcare personnel handwash
patient preoperative skin preparation
skin wound and general skin cleansing

61707 1322-86E(712)

Peel Open Here

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

Drug Facts (continued)

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

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

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

Drug Facts (continued)

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
- 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

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 1-800-548-4873
Monday through Friday 8:00 AM to 4:30 PM EST

- wet hands and forearms with water
- scrub for 3 minutes with 5 ml of solution (4 full strokes) and a wet brush paying close attention to the nails, cuticles, and interdigital space

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

PROVON[®] BRAND	
Antimicrobial Skin Cleanser	
<i>Chlorhexidine Gluconate 2% Solution - Antiseptic</i>	
Drug Facts	
Active ingredient Chlorhexidine gluconate 2% solution	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	
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