SCRUB CARE EXIDINE-2 CHG- chlorhexidine gluconate solution Xttrium Laboratories, Inc.

Drug Facts 2% Carefusion

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 cleansing

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 or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- 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 if permitted to enter and remain in the eye of 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 advised by a health care provider

Stop use and ask a doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious conditions.

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 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

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** (Mon. - Fri. 8:00 AM - 4:30 PM CST)

Package Label

NDC 0116-2992-04

REF 29900-204

BD Scrub CareTM

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate 2% Solution

Antiseptic

Non-sterile Solution

Contains:

2% Chlorhexidine Gluconate

For External Use Only

For Single Use Only

Distributed By

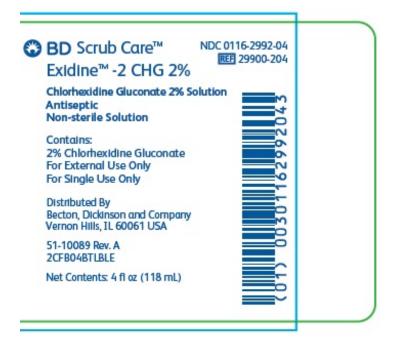
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10089 Rev. A

2CFB04BTLBLE

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

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 or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- 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 advised by a health care provider

Drug Facts (continued)

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.

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:

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Healthcare personnel handwash:

- wet hands with water
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Drug Facts (continued)

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
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Skin wound and general skin cleaning:

- thoroughly rinse the area to be cleaned with water
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- 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

Laundering/Cleaning Instructions:

Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-2992-08

REF 29900-208

BD Scrub CareTM

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains: 2% Chlorhexidine Gluconate

For External Use Only

Distributed by

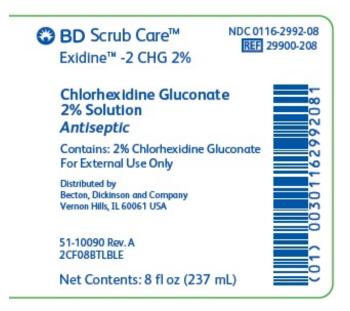
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10090 Rev. A

2CF08BTLBLE

Net Contents: 8 fl oz (237 mL)



NDC 0116-2992-16

REF 29900-216

BD Scrub Care™

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains:

2% Chlorhxidine Gluconate

For External Use Only

Distributed By

Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10091 Rev. A

2CFB16BTLLBLC

Net Contents: 16 fl oz (1 pt) (473 mL)



NDC 0116-2992-17

REF 29900-216P

BD Scrub CareTM

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains:

2% Chlorhexidine Gluconate

For External Use Only

Distributed By

Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10092 Rev. A

2CFB16BTLPLBLC

Net Contents: 16 fl oz (1 pt) (473 mL)



NDC 0116-2992-32

REF 29900-232

BD Scrub CareTM

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains: 2% Chlorhexidine Gluconate

For External Use Only



NDC 0116-2992-32 REF 29900-232

Chlorhexidine Gluconate 2% Solution Antiseptic

Contains: 2% Chlorhexidine Gluconate For External Use Only

Distributed by Becton, Dickinson and Company Vemon Hills, IL 60061 USA

51-10093 Rev. A 2CFB32BTLLBLC



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

NDC 0116-2992-33

REF 29900-232P

BD Scub Care™

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains: 2% Chlorhexidine Gluconate

For External Use Only

Distributed by

Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10094 Rev. A

2CFB32BTLPLBLC

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



NDC 0116-2992-33 REF 29900-232P

Chlorhexidine Gluconate 2% Solution Antiseptic

Contains: 2% Chlorhexidine Gluconate For External Use Only

Distributed by Becton, Dickinson and Company Vernon Hills, IL 60061 USA

51-10094 Rev. A 2CFB32BTLPLBLC



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

NDC 0116-2992-01

REF 29900-201

BD Scrub CareTM

ExidineTM-2 CHG 2%

Chlorhexidine Gluconate

2% Solution

Antiseptic

Contains:

2% Chlorhexidine Gluconate

For External Use Only

Distributed by

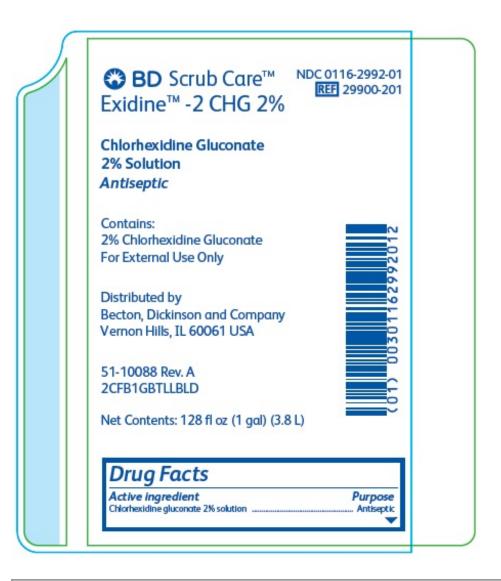
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10088 Rev. A

2CFB1GBTLLBLD

Net Contents: 128 fl oz (1 gal) (3.8 L)



SCRUB CARE EXIDINE-2 CHG

chlorhexidine gluconate solution

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0116-2992 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | | |
|---|----------------------------|------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| CHLORHEXIDINE GLUCONATE (UNII: MOR8 4MUD8 E) (CHLORHEXIDINE - UNII:R4KO0 DY52L) | CHLORHEXIDINE GLUCONATE | 2 g in 100 mL | | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W) | | |
| HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16) | | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | | |
| WATER (UNII: 059QF0KO0R) | | |

CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)

| F | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:0116-2992- 04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2010 | | |
| 2 | NDC:0116-2992- 08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2010 | | |
| 3 | NDC:0116-2992- 16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2010 | | |
| 4 | NDC:0116-2992- 17 | 473 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 05/01/2010 | | |
| 5 | NDC:0116-2992- 32 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2010 | | |
| 6 | NDC:0116-2992- 33 | 946 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 05/01/2010 | | |
| 7 | NDC:0116-2992- 01 | 3786 mL in 1 JUG; Type 0: Not a Combination Product | 05/01/2010 | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| NDA | NDA0 19 422 | 05/01/2010 | | |
| | | | | |

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

| Establishment | | | | |
|----------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Xttirum Laboratories, Inc. | | 007470579 | manufacture(0116-2992) | |

Revised: 6/2020 Xttrium Laboratories, Inc.