

Attachment # 1: NDA 20-111 -Revised labeling, 4-ounce Dyna-Hex 0.75% CHG

NDC 0116-1175-04

DYNA-HEX 0.75[®]

(Chlorhexidine Gluconate 0.75% Solution)

Antiseptic

Contains: 0.75% Chlorhexidine Gluconate

Manufactured By: Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY



N 3 0116-1175-04 1

Net Contents: 4 fl oz (118 ml)

Drug Facts

Active ingredient
chlorhexidine gluconate
0.75% solution healthcare personnel handwash

Purpose

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 meninges
- in the genital area
- as a preoperative skin preparation (especially on the head and face)

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Amendment to NDA 20-111/ (b) (4) -Revision Request

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

NDC 0116-1175-08

DYNA-HEX 0.75[®]

(Chlorhexidine Gluconate 0.75% Solution)

Antiseptic

Contains: 0.75% Chlorhexidine Gluconate

Manufactured By: Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY



N 3 0116-1175-08 9

Net Contents: 8 fl oz (237 ml)

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Drug Facts

Active ingredient chlorhexidine gluconate 0.75% solution	Purpose healthcare personnel handwash
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 meninges ■ 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	

Amendment to NDA 20-111/

(b) (4)

-Revision Request

Attachment # 2 (cont'd): NDA 20-111 -Revised labeling, 8-ounce Dyna-Hex 0.75% CHG

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
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.
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)	

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

NDC 0116-1175-16

DYNA-HEX 0.75[®]
(Chlorhexidine Gluconate 0.75% Solution)
Antiseptic

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

FOR EXTERNAL USE ONLY



Drug Facts	
Active ingredient chlorhexidine gluconate 0.75% solution	Purpose healthcare personnel handwash
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 meninges	
• 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 installed 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	
• dry thoroughly	
Other information	• store at 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F)
Inactive ingredients citric acid, concamide DEA, FD&C yellow #5, FD&C red # 4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, triclosamidopropyl trimethyl ammonium chloride	
Questions or comments? 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[®]
(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: 30 fl. oz. (887 ml)

Drug Facts	
Active ingredient chlorhexidine gluconate 0.75% solution	Purpose healthcare personnel handwash
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 • as a preoperative skin preparation (especially on the head and face) • as a general skin cleanser	• in contact with meninges • as a surgical hand scrub • in the genital area • 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 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 #40, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, nondimethylpropyl trimethyl ammonium chloride	
Questions or comments? Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM CT	

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

NDC 0116-1175-32

DYNA-HEX[®]

(Chlorhexidine Gluconate 0.75% Solution)

Antiseptic

Contains:

0.75% Chlorhexidine Gluconate

Xttrium Laboratories, Inc.

Manufactured By:

Mount Prospect, IL 60056

FOR EXTERNAL USE ONLY

3 011611775321 6

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

Drug Facts	Purpose
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	
Do not use • if you are allergic to chlorhexidine gluconate or any other ingredients • as a preoperative skin preparation (especially on the head and face) • as a general skin cleanser	• in contact with meninges • in the genital area • 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 dizziness 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: • 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, ricinamidopropyl trimethyl ammonium chloride	
Questions or comments? Call 1-773-268-5800 Monday through Friday 8:00 AM to 4:30 PM CT	

Revision Request

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
05/08/2013