DYNA-HEX 2- chlorhexidine gluconate liquid Team Technologies, Inc

Drug Facts

Chlorhexidine gluconate 2% Solution

Purposes

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

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

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
- wound 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 conditions.

Keep out of reach of children

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

Direction

• use with care in premature infants and 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 throughly 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 minutes
- dry with sterile towel
- repeat procedure for an additional 2 minutes and dry with sterile towel

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes
- dry with sterile towel
- repeat procecedure for an additional 2 minutes and dry with 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 **1-800-587-3271** Monday through Friday 8:00 AM to 4:30 PM

Package Label

NDC 0116-1021-04

DYNA-HEX 2®

(Chlorhexidine Gluconate 2% Solution)

Antispeptic

Contains: 2% Chlorhexidine Gluconate

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

For External Use Only.

Net Contents: 4 fl OZ (118 mL)

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: 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,

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.

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

DYNA-HEX 2

chlorhexidine gluconate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67659-901(NDC:0116-1021)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthCHLORHEXIDINE GLUCONATE (UNII: MOR8 4MUD8 E) (CHLORHEXIDINE -
UNII:R4KO0 DY52L)CHLORHEXIDINE
GLUCONATE2 g
in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)	
WATER (UNII: 059QF0KO0R)	

Packaging

Item Code Package Description Marketing Start Date Marketing End

NDA	NDA0 19 422	0 1/0 1/20 14				
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
Marketing Information						
1 NDC:67659-901- 98	118 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit o Package	f Co- 08/24/2016				

Labeler - Team Technologies, Inc (192339703)

Registrant - Team Technologies, Inc (192339703)

Establishment						
Name	Address	ID/FEI	Business Operations			
Team Technologies, Inc		079527756	repack(67659-901), relabel(67659-901)			

Revised: 10/2019 Team Technologies, Inc