

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207964Orig1s000

LABELING

Drug Facts (continued)

- discard each cloth after a single use
- after package has been opened, discard any unused cloths

Other information

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

Inactive ingredients

benzalkonium chloride, dimethicone emulsion, glycerin, isopropyl alcohol, propylene glycol, purified water USP



DO NOT FLUSH

Non-Sterile.

Product is not made with Natural Rubber Latex.

Cloth: 100% Polyester

REF MSC095CHG



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Manufactured by Medline Industries, Inc., Northfield, IL 60093 USA.
Made in USA with domestic and foreign materials.

Questions, comments, or ordering call: 1-800-MEDLINE

Customer Service Hours:
(Monday to Friday, 7 AM to 7 PM CST)
RI18MSC



▲
Tear Here



NDC: 53329-244-01

READYPREP™ CHG

2% CHLORHEXIDINE GLUCONATE* CLOTH

PATIENT PREOPERATIVE SKIN PREPARATION

NON-STERILE

*EQUIVALENT TO 500 MG CHLORHEXIDINE GLUCONATE PER CLOTH

- ⊕ Provides rapid bactericidal action against a broad spectrum of microorganisms
- ⊕ Significantly reduces the number of microorganisms on intact skin
- ⊕ Demonstrates continued antimicrobial activity for up to 6 hours after application

FRAGRANCE FREE

RINSE FREE

SINGLE USE ONLY.
FOR EXTERNAL USE ONLY.
DO NOT MICROWAVE.

2 9×10.5 in (22.9×26.7 cm) DISPOSABLE CLOTHS

REF MSC095CHG

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 2% solution...	Antiseptic

Uses

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

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

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds
- as a general skin cleanser

When using this product

- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

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.
- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.
- to open package: identify the tear notch labeled on the front of the package. Grasp with hands on both sides of the tear notch and tear to expose cloth.
- transfer contents onto prep table, avoiding contact between cloth and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm² area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 65 cm² area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not rinse.



NDC: 53329-244-02

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FRAGRANCE FREE RINSE FREE

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24 PACKS OF 2 CLOTHS | 9×10.5 in (22.9×26.7 cm) DISPOSABLE CLOTHS

REF MSC095CHG

Drug Facts

Active Ingredient
Chlorhexidine gluconate 2% solution

Purpose
Antiseptic

Uses
• To reduce bacteria that can potentially cause skin infection
• For preparation of skin prior to surgery

Warnings
For external use only
Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
• anaphylaxis/difficulty breathing
• hives
• facial swelling
• rash
• itching
• an allergic reaction occurs, stop use and seek medical help right away.

Do not use
• In patients allergic to chlorhexidine gluconate or any other ingredient in the product
• For lacerations or punctures or in contact with the meninges
• For open skin wounds
• As a general skin cleanser

When using this product
• Keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter the eyes. If contact occurs, flush with cool water right away and contact a doctor.
• Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. There 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.
• Do not inhale.
• Product and packaging are not sterile. Follow your hospital policy for skin preparation with nonsterile products.
• To open package: Identify the tear notch labeled on the front of the package. Grasp with thumb on both sides of the tear notch and tear to separate cloth.
• Transfer contents into prep table, avoiding contact between cloth and outside of package to reduce risk of cross-contamination.
• Use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth wet and not to compress. Use second cloth to prepare larger areas.
• Dry surgical sites (such as abdomen or arm); use one cloth to cleanse each 161 cm² area repeatedly 2 to 5 times of skin to be prepared. Vigorously scrub skin back and forth for 20 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not re-use.
• For non-surgical sites (such as genital area); use one cloth to cleanse each 161 cm² area repeatedly 2 to 5 times of skin to be prepared. Vigorously scrub skin back and forth for 20 minutes, completely wetting treatment area, then discard. Allow area to dry for one (1) minute. Do not re-use.
• Discard cloth cloth after a single use.
• After package has been opened, discard any unused cloths.

Other information
• Store product in:
• airtight container at room temperature (20-25°C (68-77°F))
• and below 40°C (104°F)

Inactive ingredients
Benzalkonium chloride, dimethylsiloxane emulsion, glycerin, isopropyl alcohol, propylene glycol, purified water USP.

REF MSC095CHG

Product is not made with Natural Rubber Latex.

DO NOT FLUSH Cloth: 100% Polyester

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
11/20/2018