

PHARMA-CARE SKIN PREPARATION CLOTHS- benzalkonium chloride cloth
Enviro Specialty Chemicals Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

PHARMA + CARE PATIENT PREOPERATIVE & POSTOPERATIVE SKIN PREPARATION CLOTHS

DRUG FACTS

ACTIVE INGREDIENT: Benzalkonium Chloride 0.13

PURPOSE: Antiseptic Skin Sanitizer

USES: For preparation of skin pre and post surgery

Helps reduce bacteria on the skin.

WARNINGS:

- Single use only
- Do not freeze
- For external use only
- Do not use in ears, eyes or mouth
- Use with care in premature infants or infants under 2 months of age
- Avoid contact with the eyes. In case of contact, flush eyes with water
- Stop use and ask a doctor if skin redness or irritation develops
- If swallowed, get medical help immediately

CAUTION: KEEP OUT OF REACH OF CHILDREN

OTHER INFORMATION:

Store product flat and between 68-77° F (20 - 25° C)

Avoid excessive heat above 104° F (40° C)

INACTIVE INGREDIENTS:

Aloe Barbadensis leaf extract, Aqua, Citric Acid, Caprylyl Glucoside, Laureth-4, Polyhexanide, Phenoxyethanol, Triethoxysilylpropyl Steardimonium Chloride.

QUESTIONS?

Call +1(888) 331-8332

Mon-Fri 9.00 AM - 5.00 PM (EST)

DIRECTIONS:

DO NOT MICROWAVE

Product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

Using sterile scissors, cut off end seal of satchel.

Transfer contents onto prep table. To reduce the risk of cloth contamination, avoid contact between cloths and the outside of package.

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 the second cloth to prepare larger areas.

For dry surgical sites such as abdomen or arm, use one cloth to cleanse each 5 in. x 5 in. area (approx. 161 sq. cm) of skin to be prepared.

Vigorously scrub skin back and forth for 3 minutes, completely wetting the treatment area. Discard cloth. Allow area to air dry for one (1)

minute. Do not rinse.

For moist surgical sites such as inguinal fold, use one cloth to cleanse 2 in. x 5 in. (approx. 65 sq. cm) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting the treatment area. Discard cloth. Allow area to air dry for one (1) minute. Do not rinse.

Discard each cloth after single use.

After satchel has been opened, discard any unused cloths.

RINSE FREE

LONG LASTING, ALCOHOL-FREE

PROTECTION FROM MICROORGANISMS

☐ *Formulated and enhanced with*

Zetrisil

☐ ***A PROPRIETARY SILICONE QUATERNARY SOLUTION***

+ Fast-acting, 15-second formula

+ Last up to 4 hours

+ No natural rubber or latex

+ Non-sterile

DO NOT MICROWAVE

Please dispose of used wipes responsibly.

Do not dispose used wipes down the toilet.

Not made with natural rubber latex.

☐ ***ESC BRANDS***

DISTRIBUTED BY: ESC BRANDS, LLC.

OLD HARGRAVE ROAD, SUITE B

LEXINGTON, NC 27295

888-331-8332

www.escbrands.com

FORMULATED IN THE USA

MADE IN CHINA

Packaging



PHARMA + CARE

PATIENT PREOPERATIVE & POSTOPERATIVE SKIN PREPARATION CLOTHS

**LONG LASTING, ALCOHOL-FREE
PROTECTION FROM MICROORGANISMS**

- + Non-sterile
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- + Fast-acting, 15-second formula
- + Last up to 4 hours
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Formulated and enhanced with **Zetrisol**

DO NOT MICROWAVE

NET CONTENTS: 24 PACKAGES (2 - 7.5 IN. X 7.5 IN. (19.1 CM X 19.1 CM) CLOTHS PER PACKAGE/48 CLOTHS PER BOX)

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2 - 7.5 in. x 7.5 in. (19.1 cm x 19.1 cm) Cloths

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MADE IN CHINA

PC-1009-01

PHARMA-CARE SKIN PREPARATION CLOTHS

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71884-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLYL GLUCOSIDE (UNII: V109WUT6RL)	
LAURETH-4 (UNII: 6HQ855798J)	
POLYHEXANIDE (UNII: 322U039GMF)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIETHOXYDILYLPROPYL STEARDIMONIUM CHLORIDE (UNII: XGN40YQC7B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71884-015-02	2 in 1 PACKET	08/14/2020	
1		26.5 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:71884-015-24	24 in 1 CASE	08/14/2020	
2		2 in 1 PACKET		
2		26.5 mL in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/14/2020	

Labeler - Enviro Specialty Chemicals Inc (202621850)