

**ANTIMICROBIAL FOAMING SANITIZER- benzethonium chloride liquid liquid
A-Cute Derm, Incorporated**

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.

DRUG FACTS

Foaming Antimicrobial Sanitizer

Active Ingredient

Benzethonium Chloride 0.2%

Antimicrobial

Inactive Ingredients

Water, Lauramidopropyl Betaine, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben.

Purpose

First Aid Antimicrobial Sanitizer

Use

Kleer-Plex is a unique, non-drying sanitizer. Designed for all skin types and pH balanced. Kills 99.9% of germs including Staph,

Pseudomonas, and E. coli. Excellent for post-operative care. May be used as a First Aid Antimicrobial to help protect against

skin infection.

Warnings

External use only. Do not use in eyes. In case of deep wounds or puncture wounds, consult a physician. If irritation develops and persists for more than a few days, discontinue use and consult a physician. .

Keep Out Of Reach Of Children

Other Information

Alcohol Free

Moisturizes

Made In USA

Questions or Comments

Bio-Medical & Pharm., Mfg. Corp.

4311 South Dr., Houston, TX 77053

Phone: 281.835.8051

Internet: www.kleerplex.com

Directions

Dispense foam into palms, then spread onto hands and other areas to be treated.

A-Cute Derm Medical Skincare

Antiseption Foam Sanitizer

NDC #: 61619-718-70

32 FL OZ(946.4

Directions

- Dispense foam into palms, then spread onto hands and other areas to be treated.
- Leave the product on the skin.

Other Information

- Antiseption™ Antimicrobial Foaming Sanitizer is an easy-to-use product that has been tested and proven to kill a wide range of pathogens preventing skin infections and post-operative complications due to bacterial infiltration of wounds.
- Proper use in a professional setting may help prevent the spread of overt skin infections and reduce the risk of infection to healthcare professionals and patients.
- Alcohol-Free.
- Moisturizes.
- Made in U.S.A.

Questions or Comments

A-Cute Derm, Inc.
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**ANTIMICROBIAL ANTISEPTION™
FOAM SANITIZER**

Refill
NDC# 61619-718-32
32.0 FL OZ (946.4 ml)

Drug Facts
Foaming Antimicrobial Sanitizer

Active Ingredients	%	Purpose
Benzethonium Chloride.....0.20		Antimicrobial

Inactive Ingredients
Water, Lauramidopropyl Betaine, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben

Purpose
• First Aid Antimicrobial Sanitizer

Uses
• Antiseption™ is a unique, non-drying sanitizer. • Designed for all skin types and pH balanced. • Kills 99.9% of germs including Staph, Pseudomonas, and E. coli. • Excellent for pre and post-operative care. • May be used as a First Aid Antimicrobial to help protect against skin infection.

Warnings
• External use only. • Do not use in eyes. • In case of deep wounds or puncture wounds, consult a physician. • If irritation develops and persists for more than a few days, discontinue use and consult a physician.

KEEP OUT OF REACH OF CHILDREN



ml)

ANTIMICROBIAL FOAMING SANITIZER

benzethonium chloride liquid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61619-718
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	
2-HEXENAL PROPYLENE GLYCOL ACETAL, (1E)- (UNII: ZBS49DF5S4)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-718-32	946 g in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/27/2015	

Labeler - A-Cute Derm, Incorporated (809845803)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-718)

Revised: 10/2015

A-Cute Derm, Incorporated