

ANTIMICROBIAL CLEANSING GEL- benzethonium chloride lotion **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

Antimicrobial

Active Ingredients

Benzethonium Chloride (0.2%)

Purpose

Antimicrobial

Uses

B-KLEER™ is a unique, non-drying cleanser. •Designed for all skin types and pH balanced. •Excellent for postoperative care. •May be used as a topical antimicrobial to help protect against skin infection.

Warnings

For external use only.

Do not use in eyes.

Ask a doctor before use if you have deep wounds or puncture wounds.

Stop use and ask a doctor if irritation develops.

Keep out of reach of children.

Directions

•Wet hands and other areas to be treated. •Place a small amount of gel in your hands and work into lather. •Apply lather to areas to be treated using a gentle, circular motion. •Rinse clean.

Other Information

•Alcohol Free •Moisturizes •Made in USA

Inactive Ingredients

Purified Water, Ammonium Lauryl Sulfate, Lauramidopropyl Betaine, Hydroxypropyl Bis-Hydroxyethyl-dimonium Chloride, Propylene Glycol, Hydroxypropylmethylcellulose, Sodium Chloride, Diazolidinyl Urea, PEG-4 Laurate, Methylparaben, Propylparaben, 3-iodo-2-propynylbutylcarbamate.

Questions or Comments

A-Cute Derm, Inc.
 1810 Cravens Road
 Stafford, TX 77477
 800.922.2883
 M-F 8:30am-5:30pm
 info@a-cutederm.com
 www.a-cutederm.com

Principal Display Panel

antimicrobial

<p>Drug Facts (continued)</p>		<p>Drug Facts</p>
<p>Directions •Wet hands and other areas to be treated. •Place a small amount of gel in your hands and work into lather. •Apply lather to areas to be treated using a gentle, circular motion. •Rinse clean.</p>		<p>Active Ingredients Purpose Benzethonium Chloride 0.20% ...Antimicrobial</p>
<p>Other Information •Alcohol Free •Moisturizes •Made in U.S.A.</p>	<p>A-CUTE DERM <small>medical skincare</small></p>	<p>Uses B-KLEER™ is a unique, non-drying cleanser. •Designed for all skin types and pH balanced. •Excellent for post-operative care. •May be used as a topical antimicrobial to help protect against skin infection.</p>
<p>Inactive Ingredients Purified Water, Ammonium Lauryl Sulfate, Lauramidopropyl Betaine, Hydroxypropyl Bis-Hydroxyethyl-dimonium Chloride, Propylene Glycol, Hydroxypropylmethylcellulose, Sodium Chloride, Diazolidinyl Urea, PEG-4 Laurate, Methylparaben, Propylparaben, 3-iodo-2-propynylbutylcarbamate.</p>		<p>B-KLEER™</p>
<p>Questions or Comments A-Cute Derm, Inc. 1810 Cravens Road Stafford, TX 77477 Item 00018 • V. 0009.2 800.922.2883 M-F 8:30am-5:30pm info@a-cutederm.com www.a-cutederm.com</p>	<p>ANTIMICROBIAL CLEANSING GEL 4.0 FL OZ (118.29 ml)</p>	
		

ANTIMICROBIAL CLEANSING GEL

benzethonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61619-104	
Route of Administration	CUTANEOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)		BENZETHONIUM CHLORIDE	2 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)				
HYDROXYPROPYL BIS-HYDROXYETHYLDIMONIUM CHLORIDE (UNII: 1EO3O1X7HG)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
PEG-4 LAURATE (UNII: AYF4VM3N1Z)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-104-04	118.29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2020	
2	NDC:61619-104-32	946.35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2020	
3	NDC:61619-104-09	1 in 1 BOX	04/29/2021	
3	NDC:61619-104-01	29.57 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:61619-104-08	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	02/20/2020		

Labeler - A-Cute Derm, Incorporated (809845803)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-104)

Revised: 4/2021

A-Cute Derm, Incorporated