

ANTISEPTATION- 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

Antiseption™ 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

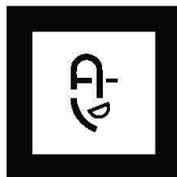
info@a-cutederm.com

www.a-cutederm.com

Principal Display Panel

Antisepation cleansing gel

Drug Facts (continued)
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 U.S.A.
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 Item 00055 • V. 0009.2 800.922.2883 M-F 8:30am-5:30pm info@acutederm.com www.acutederm.com



**A-CUTE
DERM®**
medical skincare

ANTISEPATION™

CLEANSING GEL

8.0 FL OZ (236.6 ml)

Drug Facts
Active Ingredients Purpose Benzethonium Chloride 0.20% ...Antimicrobial
Uses Antiseption™ 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.
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.



ANTISEPATION

benzethonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61619-717
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
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)

LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-717-14	118.294 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
2	NDC:61619-717-12	946.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
3	NDC:61619-717-10	1 in 1 BOX	12/22/2021	
3	NDC:61619-717-07	29.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:61619-717-28	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
5	NDC:61619-717-18	236.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/05/2016	

Labeler - A-Cute Derm, Incorporated (809845803)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-717)

Revised: 12/2021

A-Cute Derm, Incorporated