

FITEBAC SKINCARE GERMICIDAL HAND SOFTENING- benzalkonium chloride gel
fiteBac SkinCare, LLC

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.

Germicidal
Hand Softening Gel
Benzalkonium Chloride

Drug Facts

Active ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Use only a small, pea-sized amount as needed, which is enough to cover both your hands.
- Rub thoroughly over all surfaces of both hands

Other Information

- Not intended to provide ongoing protection against new germ exposure

Inactive ingredients

Cyclopentasiloxane, Dimethacone Crosspolymer, PPG-3 Benzyl Ether Ethylhexanoate, Octadecyldimethyl Trimethoxysilylpropyl Ammonium Chloride

Questions, comments, side effects or reordering

1-855-222-1640.

Distributed by fiteBac SkinCare, LLC, Marietta, Georgia 30064

PRINCIPAL DISPLAY PANEL - 85.05 g Tube Label

**GERMICIDAL
HAND SOFTENING GEL
Benzalkonium Chloride**

fiteBac™

SkinCare

"A little bit goes a long way"

- **Kills Bacteria**
- **Non-Greasy**
- **Petroleum Free**
- **Hydrophobic**
- **Alcohol Free**
- **Fragrance Free**
- **Water Free**
- **Cost-Effective**

Unique patent pending formulation kills bacteria while helping to strengthen the skin's moisture barrier. Helps keep skin velvety soft, even after frequent handwashing or exposure to gloves or other harsh environments.

NET WT 3.0 OZ (85.05g)

www.fiteBac.com

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FITEBAC SKINCARE GERMICIDAL HAND SOFTENING

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13136-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.029 mL in 29.57 mL

Inactive Ingredients

Ingredient Name		Strength		
Cyclomethicone 5 (UNII: 0THF5PCI0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13136-001-01	29.57 mL in 1 TUBE		
2	NDC:13136-001-02	88.72 mL in 1 TUBE		
3	NDC:13136-001-03	236.59 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	11/15/2011		

Labeler - fiteBac SkinCare, LLC (969593313)

Establishment			
Name	Address	ID/FEI	Business Operations
CBI Laboratories, Inc.		623704368	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
AmeriPac, Inc.		196515639	PACK

Revised: 11/2011

fiteBac SkinCare, LLC