

## **FITEBAC HAND SANITIZER- 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.*

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### **FiteBac Hand Sanitizer**

#### ***Drug Facts***

#### **Active ingredient**

Benzalkonium Chloride 0.1%

#### **Purpose**

Antimicrobial

#### **Uses**

- For hand sanitizing to decrease bacteria on the skin

#### **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
- Not intended to provide ongoing protection against new germ exposure

#### **Inactive ingredients**

Cyclopentasiloxane, Dimethicone Crosspolymer, PPG-3 Benzyl Ether Ethylhexanoate

#### **Questions, comments, side effects or reordering**

770-218-6221

Distributed by FiteBac SkinCare, LLC, Marietta, Georgia 30064

**PRINCIPAL DISPLAY PANEL**

# FiteBac<sup>®</sup>

## Hand Sanitizer

Lot # XXXXXX  
 Expires MM/YY  
 Net Wt. XXX oz (xxx g)

**Active Ingredient** - Benzalkonium Chloride  
**Inactive Ingredients** - Cyclopentasiloxane, Dimethicone  
 Crosspolymer, PPG-3 Benzyl Ether Ethylhexanoate

Reorder Part # - #####  
 Intended solely for use in FiteBac<sup>®</sup> Automatic Dispenser  
 Distributed by: FiteBac<sup>®</sup> SkinCare LLC, Marietta GA 30064

New!



### FiteBac<sup>®</sup> Hand Sanitizer



Alcohol-free

Moisturizes Skin

Kills 99.97% of germs  
 Professional's choice  
 A little goes a long way

Net Wt. 3oz (85g)  
 Benzalkonium Chloride

Use only a small amount

Patent Pending

<b>Drug Facts</b>	
<i>Active Ingredient</i>	<i>Purpose</i>
Benzalkonium Chloride 0.1% ...	Antimicrobial
<b>Uses</b> • For hand sanitizing to decrease bacteria on the skin.	
<b>Warnings</b> • For external use only.	
<b>When using this product</b> avoid contact with eyes. In case of eye contact, flush eyes with water.	
<b>Stop use and ask a doctor</b> if irritation or redness develops, or if condition persists for more than 72 hours.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Use only a small amount as needed, which is enough to cover both hands. • Rub thoroughly over all surfaces of both hands.	
<b>Inactive Ingredients</b> Cyclopentasiloxane, Dimethicone Crosspolymer, PPG-3 Benzyl Ether Ethylhexanoate	

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 Questions, comments, side effects or reordering: 770.218.6221.

FiteBac.com

Made in the U.S.A.



Tube Display

### FITEBAC HAND SANITIZER

benzalkonium chloride gel

#### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:13136-002

<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 g	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)			
	PPG-3 BENZYL ETHER ETHYLHEXANOATE (UNII: 3N703GY99W)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:13136-002-01	85 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2019	
2	NDC:13136-002-02	1000 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	
<b>Marketing Information</b>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC monograph not final	part333E	02/01/2019	

**Labeler** - FiteBac SkinCare, LLC (969593313)

### Establishment

Name	Address	ID/FEI	Business Operations
Dhaliwal Laboratories LLC		016754201	manufacture(13136-002)

Revised: 12/2020

FiteBac SkinCare, LLC