HAND SANITIZER- benzalkonium chloride gel
BLUE CROSS LABORATORIES

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.

Hand sanitizer

Active Ingredient(s)

Benzalkonium Chloride 0.12%. Purpose: Antibacterial

Purpose

Antibacterial, Hand Sanitizer

Use

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only - hands

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- do not inhale or ingest

Stop use and ask a doctor

if skin irritation develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

Inactive ingredients

Water, glycerin, propylene glycol, Aloe barbadensis leaf extract, tocopheryl acetate, fragrance, triethanolamine, carbomer

Package Label - Principal Display Panel

89 mL NDC: 22431-150-01

236 mL NDC: 22431-150-02

HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:22431-150(NDC:75729-002)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22431-150-01	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2020	
2	NDC:22431-150-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/09/2020	

Labeler - BLUE CROSS LABORATORIES (008298879)

Revised: 8/2020 BLUE CROSS LABORATORIES