

EVOWELL HAND SANITIZER WITH ALOE VERA- benzalkonium chloride liquid
Windmill Health Products, 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.

EvoWell™ Hand Sanitizer with Aloe Vera

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial and First aid antiseptic

Uses

For hand sanitizing to decrease bacteria on the skin. Recommended for repeated use. For wound sanitizing to help prevent bacterial contamination in cuts, scrapes, burns, lacerations and skin infections.

Directions

Pump onto hands as needed. Rub briskly together until dry. Pump onto wounds 3 times a day after cleaning. Allow foam to dissipate. Wipe excess with sterile gauze. May be bandaged once dry.

Inactive ingredients

ionized water, aloe vera, carbamide

Warnings

For external use only.

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

Discontinue use if irritation or redness develops. If condition persists for more than 72 hours consult a doctor.

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

Distributed by: EvoWell™ 10 Henderson Drive, West Caldwell, NJ 07006

PRINCIPAL DISPLAY PANEL - 59 mL Bottle Label

EVOWELL™
WELLNESS EVOLVED

Hand Sanitizer
with Aloe Vera

EXTENDED PROTECTION*

Eliminates 99.99% of Germs
 alcohol-free
 triclosan-free & fragrance-free
 Non-Irritating • Non-Stinging
 Benzalkonium Chloride 0.13%
 Antimicrobial
 & Antiseptic
 2.0 FL OZ
 (59 mL)

Drug Facts

Active ingredient	Purpose
Benzalkonium Chloride 0.13%	Antimicrobial and First aid antiseptic
Uses: For hand sanitizing to decrease bacteria on the skin. Recommended for repeated use. For wound sanitizing to help prevent bacterial contamination in cuts, scrapes, burns, lacerations and skin infections.	Warnings: For external use only. When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.
Directions: Pump onto hands as needed. Rub briskly together until dry. Pump onto wounds 3 times a day after cleaning. Allow foam to dissipate. Wipe excess with sterile gauze. May be bandaged once dry.	Discontinue use if irritation or redness develops. If condition persists for more than 72 hours consult a doctor.
Inactive ingredients ionized water, aloe vera, carbamide	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

*Studies show Benzalkonium Chloride protects against infection for more than three hours. Made in the U.S.A.

EVOWELL HAND SANITIZER WITH ALOE VERA			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74154-005
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6 Y)	Benzalkonium Chloride	130 mg in 100 mL
Inactive Ingredients			
	Ingredient Name		Strength
	water (UNII: 059QF0KO0R)		

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aloe vera leaf (UNII: ZY8 1Z83H0X)	
urea (UNII: 8W8 T17847W)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74154-005-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	04/27/2020	

Labeler - Windmill Health Products, LLC (831136267)

Establishment			
Name	Address	ID/FEI	Business Operations
Cemi International		015038336	MANUFACTURE(74154-005)

Revised: 4/2020

Windmill Health Products, LLC