

GEA COSMETICS LABS HAND AND BODY SANITIZER- benzalkonium chloride

0.13% spray

Romano Group, 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.

GEA Cosmetics Labs Hand & Body Sanitizer

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Uses

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For External Use only.

Do Not Use

On children less than 2 months of age
on open skin wounds

When using this product

keep out of eyes, ears, and mouth, in case of contact with eyes, rinse eyes thoroughly with water

Keep out of reach of children.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store between 15-30C (59-86F)

Avoid Freezing and excessive heat above 40C (104F)

Inactive Ingredients

Ionized water, Carbamide

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81237-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.61 g in 472 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81237-001-16	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	
2	NDC:81237-001-10	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2021	

Labeler - Romano Group, LLC (037493262)

Revised: 1/2021

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