ALCOHOL-FREE ANTISEPTIC GEL- benzalkonium chloride gel
Bioagaves de la Costa, S.A. de C.V.

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.

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Use

Hand sanitizer to help reduce bacteria that can potencially cause disease.

For use when soap and water are not available.

WARNINGS

Do not freeze. For external use only.

DO NOT USE

- In 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.

Stop use and ask a doctor if irritation or rash occurs.

These may be signs of a serious condition.

Keep out of reach of children.

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

Directions

- Place just one drop on hands to cover all surfaces.

OTHER INFORMATION

- Store below 110F (43C)
- May discolor certain fabrics or surfaces

INACTIVE INGREDIENTS

Water, hyroxyethyl cellulose, glycerin, methylparaben, propylene glycol, DMDM H

ALCOHOL-FREE ANTISEPTIC GEL
benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76598-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76598-010-01	4 mL in 1 POUCH; Type 0: Not a Combination Product	04/24/2020	
2	NDC:76598-010-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:76598-010-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:76598-010-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
5	NDC:76598-010-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
6	NDC:76598-010-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
7	NDC:76598-010-07	4500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
8	NDC:76598-010-08	20000 mL in 1 JUG; Type 0: Not a Combination Product	04/24/2020	
9	NDC:76598-010-09	200000 mL in 1 JUG; Type 0: Not a Combination Product	04/24/2020	
10	NDC:76598-010-10	1000000 mL in 1 JUG; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

Labeler - Bioagaves de la Costa, S.A. de C.V. (814644548)

Establishment

Name	Address	ID/FEI	Business Operations
Bioagaves de la Costa, S.A. de C.V.		814644548	manufacture(76598-010)

Revised: 8/2020

Bioagaves de la Costa, S.A. de C.V.