

ZOONO HAND SANITIZER- benzalkonium chloride solution
ZOONO USA, 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.

Zoono Hand Sanitizer

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose:

Antiseptic

Uses:

For Personal hand sanitizing and to reduce bacteria on the skin. Recommended for repeated use.

Warnings:

For external use only.

Do not use in the eyes

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 and redness develops.

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

Inactive Ingredients:

Ethyl alcohol, Fragrances, Silica Complex (3-Trimethoxysilyl Propyl Dimethyl Octadecyl Ammonium Chloride), Water

Questions?

Telephone 1-844-966-6687 Monday through Friday 8:00am till 5:00pm EST

Directions:

Apply liberally to hands and gently rub until dry.



Drug Facts Active Ingredient Purpose Benzalkonium Chloride 0.13%.....Antiseptic	Drug Facts (Continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Uses For personal hand sanitizing and to reduce bacteria on the skin. Recommended for repeated use.	Directions Apply liberally to the hands and gently rub until dry.
Warnings For external use only. Do not use in the eyes.	Inactive ingredients Ethyl Alcohol, Fragrances, Silica Complex 3-(Trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride, Water.
When using this product avoid contact with eyes. In case of eye contact flush eyes with water.	Questions? Telephone: 1-844-966-6687 Monday through Friday 8:00am till 5:00pm EST
Stop use and ask a doctor if irritation and redness develop	

*Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds; lasting effects for up to 24 hours.

Distributed by: Zoono USA, LLC
1151 Broad Street
Shrewsbury, NJ 07702
Formulated by Zoono Limited NZ
Made in the U.S.A. www.ZoonoUSA.com

ZOONO HAND SANITIZER

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69221-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69221-203-03	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2016	
2	NDC:69221-203-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2016	

3	NDC:69221-203-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2016	
4	NDC:69221-203-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2016	
5	NDC:69221-203-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2016	
6	NDC:69221-203-07	8 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/09/2016	

Labeler - ZOONO USA, LLC (073623478)

Establishment

Name	Address	ID/FEI	Business Operations
Zoono USA, LLC		073623478	label(69221-203)

Revised: 5/2017

ZOONO USA, LLC