

ZOONO WOUND CLEANSER- 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 Wound Cleanser

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose:

Antiseptic

Uses:

Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers, cracked skin and lips. Topical antiseptic to help decrease the risk of skin infections.

Warnings:

For external use only.

Do not use on children under 2 years of age unless directed by a doctor.

When using this product avoid contact with eyes. In case of eye contact flush eyes with water. Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

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

Inactive Ingredients:

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

Questions or Comments?

Telephone 1-844-966-6687
Monday through Friday

8:00am till 5:00pm EST

Directions:

Wound cleansing for adults and children 2 years of age or older: Spray the affected area to clean dirt and debris, use a small amount of the product and wipe it off with a sterile gauze.

For use as First Aid antiseptic for adults and children years of age or older:

Clean the affected area. Spray a small amount of this product on the area 1 to 3 times daily or as needed. Wipe off excess with sterile gauze and allow to dry. Cover affected area with a sterile bandage if needed. When bandaged, let dry first
For children under 2 years of age please consult a doctor.

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

ZOONO WOUND CLEANSER

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69221-204
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:69221-204-02	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2016	
2	NDC:69221-204-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2016	
3	NDC:69221-204-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/23/2016	

Labeler - ZOONO USA, LLC (073623478)**Establishment**

Name	Address	ID/FEI	Business Operations
Zoono USA, LLC		073623478	label(69221-204)

Revised: 10/2018

ZOONO USA, LLC