

FIRST AID ANTISEPTIC- benzalkonium chloride spray
Water-Jel Technologies

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.

First Aid Antiseptic Spray

Active ingredient

Benzalkonium chloride 0.13%

Purpose

First aid antiseptic

Uses

first aid to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only

Do not use

- in the eyes or apply over large areas of the body
- longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

- deep or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if

- the condition persists or gets worse

Keep out of the reach of children

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

Directions

- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Other information

- shake well
- store at room temperature
- you may report a serious adverse reaction to this product to 1-800-275-3433

Inactive ingredients

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol-9, propylene glycol, propylparaben, triethanolamine, water

Questions or comments?

1-800-275-3433 info@waterjel.com www.waterjel.com
 Manufactured by Water-Jel Technologies, Inc., 50 Broad Street,
 Carlstadt, NJ 07072, USA

Principal Display Panel

Drug Facts		
Active ingredient Benzalkonium chloride 0.13%	Purpose First aid antiseptic	
Uses first aid to help prevent infection in minor cuts, scrapes and burns		First Aid Antiseptic Spray Benzalkonium chloride 0.13% Helps Prevent Infection <ul style="list-style-type: none"> • For minor cuts and burns • Helps prevent infection • Non-aerosol spray • Soothes discomfort Manufactured by Water-Jel Technologies, Inc. 50 Broad Street, Carlstadt, NJ 07072 2 Fl. Oz. (59 mL)
Warnings For external use only		
Do not use		
<ul style="list-style-type: none"> ■ in the eyes or apply over large areas of the body ■ longer than 1 week unless directed by a doctor 		
Ask a doctor before use if you have		
<ul style="list-style-type: none"> ■ deep or puncture wounds, animal bites, or serious burns 		
Stop use and ask a doctor if		
<ul style="list-style-type: none"> ■ the condition persists or gets worse 		
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		
Directions ■ clean the affected area ■ spray a small amount of this product on the area 1 to 3 times daily ■ may be covered with a sterile bandage ■ if bandaged, let dry first		
Other information		
<ul style="list-style-type: none"> ■ store at room temperature ■ you may report a serious adverse reaction to this product to 1-800-275-3433 		
Inactive ingredients diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, triethanolamine, water		
Questions or comments? 1-800-275-3433 info@waterjel.com www.waterjel.com		
		

FIRST AID ANTISEPTIC

benzalkonium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-401
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	

GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZD)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-401-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/22/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2010	

Labeler - Water-Jel Technologies (155522589)

Registrant - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-401)

Revised: 12/2020

Water-Jel Technologies