DISINFECTANT- benzalkonium chloride spray Shanghai Hutchison Whitecat Co., Ltd.

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.

Disinfectant

Disinfectant

Active Ingredient(s)

BENZALKONIUM CHLORIDE 0.5g/100mL. Purpose: Antiseptic

Purpose

Antiseptic, Disinfectant

Use

Spray on human skin or surface to disinfect

Warnings

For external use only. Flammable. Keep away from heat or flame

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.

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

Directions

- Spray on human skin or surface to disinfect
- 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

WATER

Package Label - Principal Display Panel





DISINFECTANT

benzalkonium chloride spray

Product Informa	tıon	l
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:77260-301

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -	BENZALKONIUM	0.5 g

UNII:7N6JUD5X6Y)	CHLORIDE	in 100 mL
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Inactive Ingredients				
Ingredient Name	Strength			
ALCOHOL (UNII: 3K9958V90M)				
LAURETH-4 (UNII: 6HQ855798J)				
WATER (UNII: 059QF0KO0R)				

1	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77260-301-01	320 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77260-301-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Shanghai Hutchison Whitecat Co., Ltd. (545844784)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shanghai Hutchison Whitecat Co., Ltd.		545844784	manufacture (77260-301)	

Revised: 5/2020 Shanghai Hutchison Whitecat Co., Ltd.