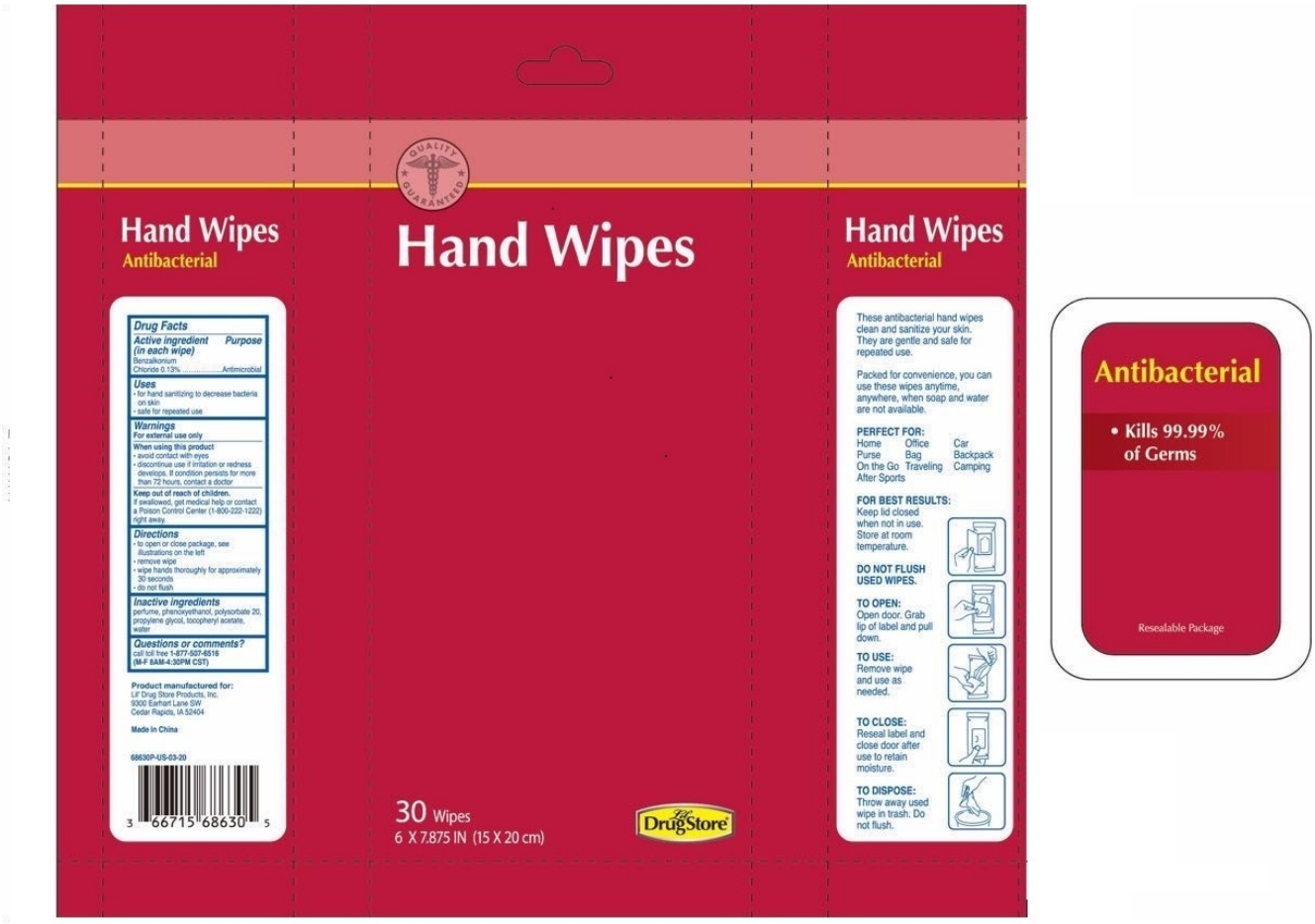
ANTIBACTERIAL WIPES- benzalkonium chloride swab
Orazen Inc

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.

Drug Facts

Active Ingredient(s)



Benzalkonium Chloride 0.13 % v/v. Purpose: Antiseptic

Purpose

Antibacterial, Wipe

Use

Decrease bacteria on skin. For use when soap and water are not available.

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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Directions

- Apply to hands
- allow skin to dry without wiping
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

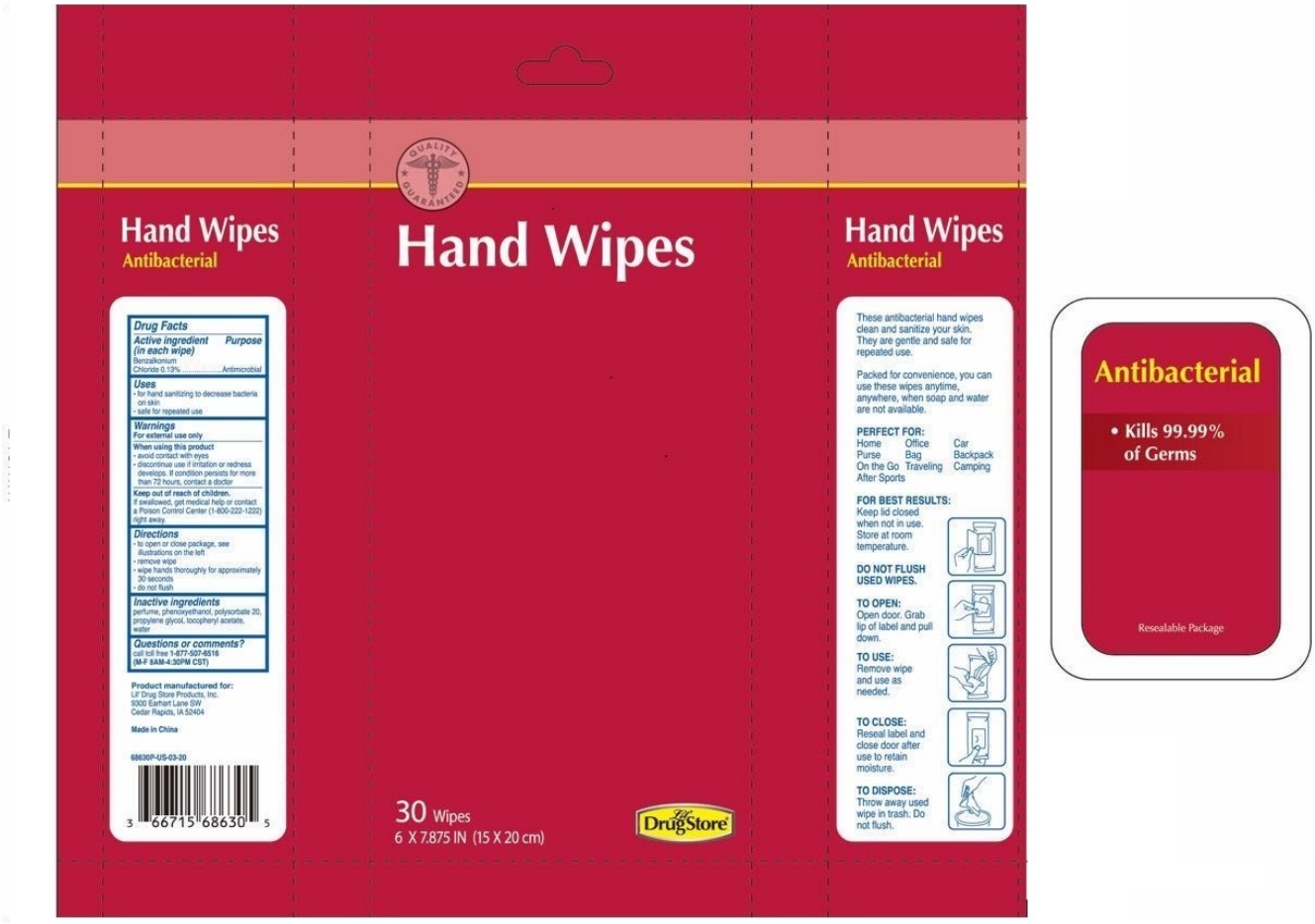
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Propylene Glycol, Phenoxyethanol, Polysorbate 20, Tocopheryl Acetate, Fragrance

Package Label - Principal Display Panel

30ct NDC: 69821-001-25



ANTIBACTERIAL WIPES

benzalkonium chloride swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71927-010
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 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-010-01	0.1 mL in 1 POUCH; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

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

Labeler - Orazen Inc (080916640)

Establishment

Name	Address	ID/FEI	Business Operations
Orazen Inc		080916640	relabel(71927-010)

Establishment

Name	Address	ID/FEI	Business Operations
Zhegiang Qimei Commodity Co/ Ltd		544331136	manufacture(71927-010)

Revised: 5/2020 Orazen Inc