

ULTRACRUZ ANTIBACTERIAL NONE- benzalkonium chloride lotion
Cixi Zhixin Bird Clean-care Product 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.

Ultracruz Antibacteria Lotion

Active Ingredient:

Benzalkonium Chloride 0.1%

Purpose:

Antiseptic

Uses:

Kill germs while soothing skin. Contains Vitamin E and Aloe Vera

Directions:

Aquirt as needed into your palms and thoroughly spread on both hands

Warnings

For external use only

Flammable. Keep away from fire or flame

Do not apply around eyes. Do not use in ears & mouth

When using this product, avoid contact with eyes. In case of contact, flush eyes with water

Stop use and see a doctor if irritation or redness develop and persist for more than 72 hours

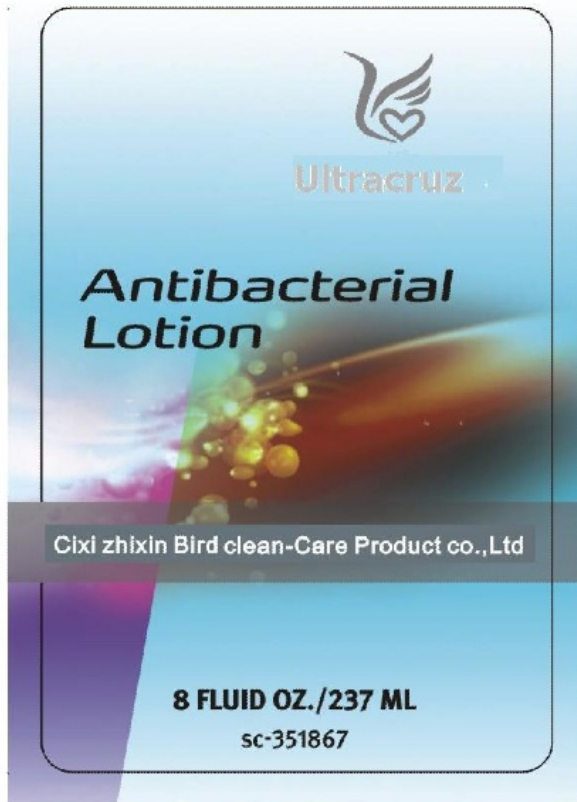
Keep out of reach of children. Children must be supervised in use of this product.

Other Information:

Store at 20C (68-77F). May discolor fabrics

Inactive Ingredient:

Deionized water, Vitamin E, Aloe vera, Glycerol, Boric acid, Carbomer, TX-20, Triethanolamine, White oil, Fragrance



**8oz ANTIBACTERIAL
HAND LOTION**

Instant Hand Sanitizer Lotion. Can be used anytime, anyplace, without water or towels. Contains moisturizers and vitamin E to leave hands feeling refreshed, soft and smooth without stickiness or residue.

Drug Facts		Lot# 1213389599
Active Ingredient	Purpose	
Benzalkonium Chloride 0.10%	Antiseptic	
Uses: Kills germs while soothing skin. Contains Vitamin E and Aloe Vera.		
Directions: Squirt as needed into your palms and thoroughly spread on both hands.		
Warnings		
For external use only.		
Flammable. Keep away from fire or flame.		
Do not apply around eyes. Do not use in ears & mouth.		
When using this product, avoid contact with eyes.		
In case of contact flush eyes with water.		
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.		
Keep out of reach of children. Children must be supervised in use of this product.		
Other Information: Store at 20° C (68° to 77° F). May discolor fabrics.		
Inactive Ingredients: Deionized water, Benzalkonium Chloride, Vitamin E, Aloe vera, Glycerol, boric acid, Carbomer, TX-20, Triethanolamine, white oil, fragrance		
Cixi zhixin Bird clean-Care Product co.,Ltd Made in China		

ULTRACRUZ ANTIBACTERIAL NONE

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49877-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	96.105 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
GLYCEROL FORMAL (UNII: 3L7GR2604E)	
ALOE (UNII: V5VD430YW9)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
BORIC ACID (UNII: R57ZHV85D4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49877-011-01	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/22/2014	

Labeler - Cixi Zhixin Bird Clean-care Product Co., Ltd. (529823986)

Registrant - Cixi Zhixin Bird Clean-care Product Co., Ltd. (529823986)

Establishment

Name	Address	ID/FEI	Business Operations
Cixi Zhixin Bird Clean-care Product Co., Ltd.		529823986	manufacture(49877-011)

Revised: 8/2014

Cixi Zhixin Bird Clean-care Product Co., Ltd.