

ASSURED- benzalkonium chloride lotion
TIANJIN YANSHENG INDUSTRIAL TRADE COMPANY

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.

Active ingredient

Benzalkonium chloride 0.115%

Purpose

Antibacterial

Use decreases bacteria on skin

Warnings

For external use only

Do not use

-over large areas of the body if you are allergic to any of the ingredients

When using this product avoid contact with eyes and face.

If contact occurs, flush thoroughly with water.

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours

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

Directions

-for adults and children of 2 years and over use on hands and face to clean and refresh, allow skin to air dry.

-For children under 2 years ask a doctor before using

Inactive ingredient

Water, propylene glycol, glycerin, cocamidopropyl betaine, polyaminopropyl biguanide, aloe barbadensis leaf extract, tocopheryl acetate, peg-54 hydrogenated castor oil, disodium edta, citric acid, fragrance, methylchloroisothiazolinone, methylsothiazolinone



ASSURED

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70031-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-54 HYDROGENATED CASTOR OIL (UNII: 0WZF1506N9)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYL SOYATE (UNII: 808DL597QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70031-002-02	20 in 1 BAG	08/31/2016	
1	NDC:70031-002-01	.1 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/31/2016	

Labeler - TIANJIN YANSHENG INDUSTRIAL TRADE COMPANY (679914791)

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