DURISAN- benzalkonium chloride liquid Sanit Technologies LLC

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 0.1%

Purpose

Antiseptic

Use

To decrease bacteria on the skin.

Warnings

For external use only.

When using this product keep out of eyes. In case of contact eyes with water.

Stop use and consult a doctor if irritation or redness develops.

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

Directions

- Pump onto dry skin. Lather vigorously for 20 seconds.
- Rinse hands and dry thoroughly.

Inactive ingredients

Water, cocamidopropyl betaine, glycerin, cetrimonium chloride, benzyl alcohol, disodium EDTA, fragrance, benzoic acid, sorbic acid, citric acid, violet 2 (CI 60730)

Package Label - Principal Display Panel



DURISAN

benzalkonium chloride liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71120-115	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)				
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)				
SORBIC ACID (UNII: X045WJ989B)				
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)				
D&C VIOLET NO. 2 (UNII: 350 KA7O6 HK)				

Packaging

# Item Code	Package Descr	ription	Marketing Start Date	Marketing End Date			
1 NDC:71120-115-01	300 mL in 1 PACKAGE; Type 0: Not a Combination Product		10/08/2020				
Marketing Information							
Marketing Categ	ory Application Number or	Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not	final part333A		10/08/2020				

Labeler - Sanit Technologies LLC (075711022)

Revised: 10/2020 Sanit Technologies LLC