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.

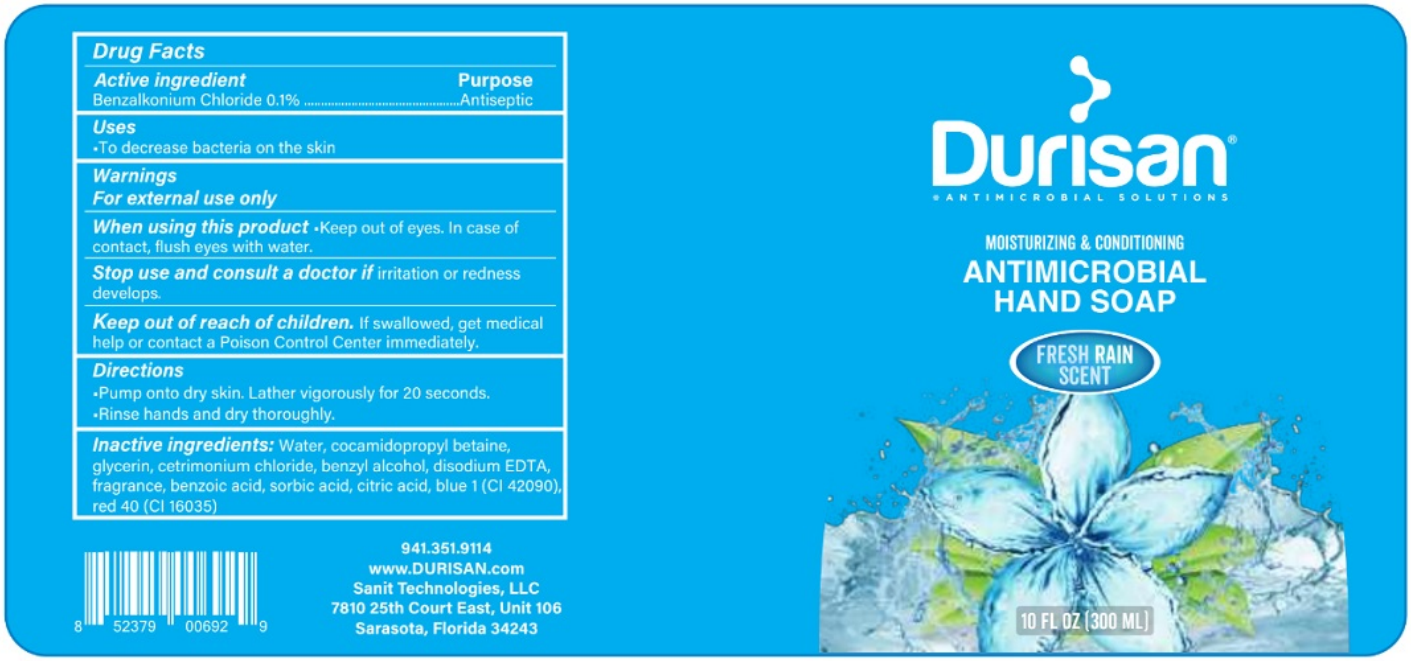
Directions

- 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, blue 1 (CI 42090), red 40 (CI 16035)

Package Label - Principal Display Panel



DURISAN

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71120-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71120-114-01	300 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	

Marketing Information

Marketing Category	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