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.

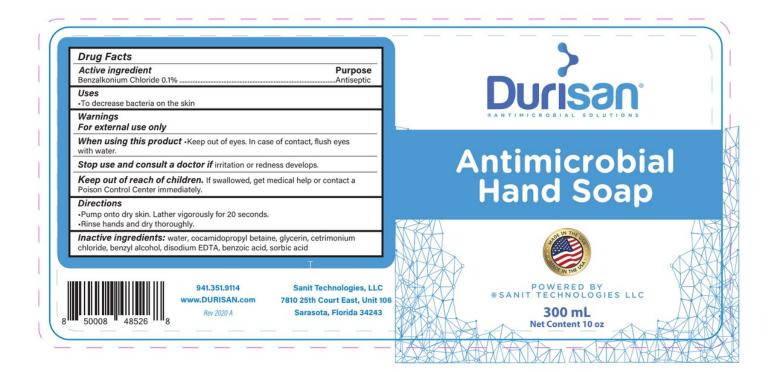
Directions

- 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, benzoic acid, sorbic acid

Package Label - Principal Display Panel



DURISAN

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71120-117
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: 50CF3011KX)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5IBP)		
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)		

Pack	aging			
# I	tem Code	Package Description	Marketing Start Date	Marketing End Date

		300 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
2	NDC:71120-117-02	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
3	NDC:71120-117-03	$3785\ mL$ in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
4	NDC:71120-117-04	50 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
5	NDC:71120-117-05	550 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
6	NDC:71120-117- 06	250 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/08/2020	
7	NDC:71120-117-07	1000 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)

Establishment				
Name	Address	ID/FEI	Business Operations	
Durisan		085479946	manufacture(71120-117)	

Revised: 12/2020 Sanit Technologies LLC