

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



Antimicrobial Hand Soap



POWERED BY
SANIT TECHNOLOGIES LLC

300 mL
Net Content 10 oz

Drug Facts

Active ingredient Benzalkonium Chloride 0.1%	Purpose Antiseptic
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Uses
•To decrease bacteria on the skin

Warnings
For external use only

When using this product •Keep out of eyes. In case of contact, flush 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 immediately.

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



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Rev 2020 A

Sanit Technologies, LLC
7810 25th Court East, Unit 106
Sarasota, Florida 34243

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: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:71120-117-01	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