

OOSAFE DISINFECTANT- benzalkonium chloride liquid SparMed ApS

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.

Purpose

Drug Facts	
Active ingredients	Purpose
Benzalkonium Chloride 0.26%	Antiseptic

Active Ingredients

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Active ingredients
Benzalkonium Chloride 0.26%

Oosafe Application

*Uses
Benzalkonium helps effectively reduce bacteria, fungi
(Candida albicans), and protozoans on the skin.

Oosafe dosage

Directions
Apply enough product in your palm to cover hands and rub hands together briefly until dry.

Oosafe warning

Warnings
For external use only.
When using this product do not use in or near the eyes.
Stop use and ask a doctor if irritation or rash appears and lasts.
Keep out of reach of children.

Oosafe childrens warning

Keep out of reach of children.

InActive Ingredients

Drug Facts (continued)
Other information Store at 64.4 - 80.4 °F (18 - 27° C).
Inactive ingredients Water, Propylene Glycol
First Aid Eye contact: In case of contact, rinse eyes thoroughly with water. Ingestion of substance: get medical help or contact a Poison Control Center right away.

Oosafe Display Panel



OOSAFE DISINFECTANT

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52759-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	2.6 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	993.7 g in 1 L
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	3.7 g in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52759-400-00	0.05 L in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	11/30/2020
2	NDC:52759-400-05	1 in 1 BOX	04/30/2012	11/30/2020
2		0.5 L in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:52759-400-50	1 in 1 BOX	04/30/2012	11/30/2020
3		5 L in 1 TANK; 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	04/30/2012	11/30/2020

Labeler - SparMed ApS (311811306)

Revised: 1/2019

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