

ULTRACARE FOR HANDS - benzalkonium chloride liquid
Coltene Whaledent Inc

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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Use hand sanitizer to reduce bacteria on the skin.

Warnings

For external use only

When using this product avoid contact with eyes.

In case of eye contact, flush with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Place enough product in palm to thoroughly cover all surfaces of both hands

Rub hands together briskly until dry

No rinsing required

Inactive Ingredients

Water, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, citric acid

Ultracare

For Hands

Alcohol Free Antiseptic Handwash

Formulated to reduce the number of germs on the hands that can cause infection and illness.

Use on clean, non-soiled hands any time when rinsing with water is not available.

Alcohol free, so it can be used in any area without fear of it creating a flammable atmosphere.

Manufactured for

Ultronics

Cuyahoga Falls, OH 44223

www.UltronicsUSA.com Tel. (800) 262-6262

1000 ml 33.8 fl. oz. Made in USA P/N

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51614-0001
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)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51614-0001-1	1000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2012	

Labeler - Coltene Whaledent Inc (622185718)

Establishment

Name	Address	ID/FEI	Business Operations
Woodbine Products Company		004220323	manufacture

Revised: 6/2012

Coltene Whaledent Inc