

ANTIBACTERIAL- benzalkonium chloride liquid
Brands International Corporation

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.

Antibacterial Soap

Benzalkonium Chloride - 0.13%

Purpose - Antibacterial

Uses for handwashing or decrease bacteria to the skin

For external use only

Stop use and ask a doctor if irritation or redness develops

When using the product

- do not get into eyes. If contact occurs, rinse eye thoroughly with water

Keep out of reach of children

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

Directions

- Wet Hands
- Apply palmful to hands
- Scrub thoroughly
- Rinse

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow# 5 (CI 19140), Red# 4 (CI14700)





Drug Facts		Antibacterial Liquid Soap
Active Ingredients	Purpose	
Benzalkonium Chloride 0.13 %	Antibacterial	 <p>524741624</p> <p>Serie Manufacturing Inc. LMI 112 Made in Canada</p>
Uses for handwashing or decrease bacteria to the skin		
Warnings For external use only.		
Stop use and ask a doctor if irritation or redness develops.		
When using this product		
• do not get it into eyes, if contact occurs, rinse eye thoroughly with water		
Keep out of reach of children		
If swallowed, get medical help or contact a Poison Control Center right away.		
Directions • wet hands • apply palmful to hands • scrub thoroughly • rinse		
Other Ingredients		
Water, Sodium Lauryl Sulfate, Cocamidopropyl betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance, Tetrasodium EDTA, Methylchloro-benzothiazolone, Methylchloro-benzothiazolone, Yellow 8 (CI 19140), Red 44 (CI 14700).		

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-001-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2016	
2	NDC:50157-001-60	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/08/2016	

Labeler - Brands International Corporation (243748238)