LUVONE HAND ANTIBACTERIAL CITRIC- benzalkonium chloride liquid
INDUSTRIAS MC CLEAN S A S

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.

Luvone liquid Hand soap antibacterial Citric

Drug Facts

Active Ingredients

Benzalkonium Chlorie 0.13%

Purpose

Antibacterial

Use(S)

For hand washing to decrease bacteria on the skin.

Warning(S)

For external use only. Hnads only.

Do not use

- In children less than 2 months of age.
- On open skin wounds.

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. Conditions 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

- Pum into hands, wet as nedeed.
- Lather vigorously for at least 15 seconds
- Wash skin, rinse thoroughly and dry.

Other Information

- Store at room temperature, in a cool and dry place.

Inactive Ingredients

Aqua, Cetrimonium Choride, Glycerin, Lauramidopropylamine Oxide, Cocamidopropyl betaine, Cocoamido MEA, Coco-Glucoside (and) Glyceryl Oleate, PEG-150 Distearate, Citric Acid, edetate disodium, Parfum, CI 42090, CI 47005.

Package Labeling:

LUVONE HAND ANTIBACTERIAL CITRIC

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80683-004
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
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80683-004-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/01/2021	

Labeler - INDUSTRIAS MC CLEAN S A S (886518381)

Revised: 7/2021 INDUSTRIAS MC CLEAN S A S