

## **LUVONE HAND ANTIBACTERIAL ROSES- 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.*

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### **Luvone liquid Hand soap antibacterial Roses**

#### ***Drug Facts***

#### ***Active Ingredients***

Benzalkonium Chloride 0.13%

#### ***Purpose***

Antibacterial

#### ***Use(S)***

For hand washing to decrease bacteria on the skin.

#### ***Warning(S)***

**For external use only. Hands 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 needed.
- 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 Chloride, Glycerin, Lauramidopropylamine Oxide, Cocamidopropyl betaine, Cocoamido MEA, Coco-Glucoside (and) Glyceryl Oleate, PEG-150 Distearate, Citric Acid, edetate disodium, Parfum, CI 17200.

## Package Labeling:

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13% ....	Antibacterial
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<b>Warning(s)</b>	
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<ul style="list-style-type: none"> <li>• In children less than 2 months of age.</li> <li>• On open skin wounds.</li> </ul>	
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<b>Keep out of reach of children.</b>	
If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Pump into hands, wet as needed.</li> <li>• Lather vigorously for at least 15 seconds</li> <li>• Wash skin, rinse thoroughly and dry.</li> </ul>	
<b>Other Information</b>	
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<b>Inactive Ingredients</b>	
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**KILLS 99,9% OF GERMS**

**LUVONE**  
**LIQUID HAND SOAP**  
**ANTIBACTERIAL**

**FREE**  
FROM PARABENS  
PHTHALATES,  
SILICONES.

**ROSES**

**Moisturizing conditioners**  
**Gentle cleaners**

**16.91 Fl. Oz**  
**500 mL**

Empty & Recycle Here  
**PLASTIC BOTTLE**

**Imported and distributed by:**  
**Industrias Mc Clean Llc**  
Orlando, FL 32832  
1-407-479-8280  
Made in Colombia

**Manufactured by:**  
**Industrias Mc Clean S.A.S**  
Parque Industrial Celta Trade Park,  
Bodega 48 Int 2.  
Funza - Cundinamarca  
PBX: (+57) 8237706  
servicioalcliente@mcclean.com.co  
www.mcclean.com.co

[www.luvone.com.co](http://www.luvone.com.co)  
[www.luvone.us](http://www.luvone.us)

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## LUVONE HAND ANTIBACTERIAL ROSES

benzalkonium chloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80683-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LAURAMIDOPROPYLAMINE OXIDE</b> (UNII: I6KX160QTV)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>COCO MONOETHANOLAMIDE</b> (UNII: C80684146D)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80683-005-01	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