

LUVONE ANTIBACTERIAL SANITIZER- alcohol gel
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 Antibacterial Sanitizer Gel

Drug Facts

Active Ingredients

Ethyl Alcohol 70 %

Purpose

Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning(s)

For external use only. Flammable. Keep away from heat or flame.

Do not use

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

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor

if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

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

Directions

- Place enough product on hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store between 15 - 30 °C (59 - 86 °F).
- Avoid freezing and excessive heat about 40 °C (104 °F).

Inactive Ingredients

Water (Aqua), Fragrance (Parfum), Carbomer, Glycerin, Propylene Glycol, Triethanolamine, and Tocopheryl Acetate

Package Labeling:

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LUVONE

ANTIBACTERIAL SANITIZER GEL

CONTENT
16.9 FL. OZ.
500ml

MADE IN COLOMBIA
NSOC99504-20CO
IMPORTED BY
Mc Clean USA
Orlando, FL 00000
1-123-456-7890
www.mcclean.com.co

Mc Clean
Always at Home



LUVONE ANTIBACTERIAL SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80683-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80683-000-01	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)

Establishment			
Name	Address	ID/FEI	Business Operations
INDUSTRIAS MC CLEAN S A S		886518381	manufacture(80683-000)

Revised: 10/2020

INDUSTRIAS MC CLEAN S A S