

LUVONE BODY WASH DAILY MOISTURIZING OATMEAL- 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 Body Wash Daily Moisturizing Oatmeal

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.

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

- Pump 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

Water, Sodium Laureth Sulfate, Cocamidopropyl betaine, Glycerin, Sodium laureth sulphate (and) Cocoamido MEA (and) Glycol Stearate (and) Gycol, Sodium Chloride, Lauramidopropylamine Oxide, Coco-Glucoside (and) Glyceryl Oleate, PEG-150 Distearate, Edetate Disodium, Citric Acid, Parfum, *Avena sativa extract*, DMDM Hydantoin and Iodopropynyl Butylcarbamate, CI 15510.

Package Labeling:

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Imported and distributed by:
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Made in Colombia

Manufactured by:
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16.91 Fl. Oz
500 mL

7 709184 436997

LUVONE BODY WASH DAILY MOISTURIZING OATMEAL

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80683-002
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)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80683-002-01	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

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