MEDSHIELD PRODUCTS- antiseptic liquid liquid HWL Holdings, LLC

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.

MedShield 5-Gallon Liquid Spray

Active Ingredient(s)

Benzalkonium Chloride 0.13% Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For disinfecting all topical areas.

Warnings

For external use only-hands

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

if skin irritation develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Spray thoroughly over entire body.

Inactive ingredients

*1,2,3-Trihydroxypropane, water

Package Label - Principal Display Panel



Drug Facts

Active ingredient **Purpose** Benzalkonium Chloride 0.13%......Antiseptic

Uses for disinfecting all topical areas

Warnings

For external use only-hands

When using this product keep out of eyes ■In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if skin irritation develops.

Keep out of reach of children.

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

Directions

· Spray thoroughly over entire body.

Inactive ingredients

*1,2,3-Trihydroxypropane, water

Distributed by MedShield US Distributed by: MedShield US P.O. Box 600979, North Miami, FL 33160 Questions and Concerns? info@medshieldproducts.com www.medshieldproducts.com



NDC: 75446-113-33 FDA REGISTERED

20000 mL NDC: 75446-113-33

MEDSHIELD PRODUCTS

antiseptic liquid liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75446-113

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 ug in 1 mL

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KO0R)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:75446-113- 33	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2020			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	04/27/2020				

Labeler - HWL Holdings, LLC (058630887)

Establishment					
Name	Address	ID/FEI	Business Operations		
HWL Holdings, LLC		058630887	manufacture(75446-113)		

Revised: 8/2020 HWL Holdings, LLC