MEDSHIELD PRODUCTS- hand sanitizer gel gel
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 Gel

Active Ingredient(s)

Benzalkonium Chloride 0.1% Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

to decrease bacteria on the skin that could cause disease

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

- Rub thoroughly over all surfaces of both hands.
- Rub hands together briskly until dry.

Other information

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

Inactive ingredients

aloe oil, *carbomer, *carbopol aqua SF-1, glycerol, *hydroxyethyl cellulose, *hydroxypropyl methyl cellulose, sodium hydroxide, water

*contains one or more of these ingredients

Package Label - Principal Display Panel

236 mL NDC: 75446-222-17

MEDSHIELD PRODUCTS

hand sanitizer gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75446-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 ug in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:75446-222-03	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
2	NDC:75446-222-05	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
3	NDC:75446-222-07	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
4	NDC:75446-222-09	75 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
5	NDC:75446-222-11	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
6	NDC:75446-222-13	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
7	NDC:75446-222-15	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
8	NDC:75446-222-17	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
9	NDC:75446-222-19	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
10	NDC:75446-222-21	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
11	NDC:75446-222-23	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
12	NDC:75446-222-25	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
13	NDC:75446-222-27	1183 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
14	NDC:75446-222-29	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
15	NDC:75446-222-31	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
16	NDC:75446-222-33	10000000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
17	NDC:75446-222-35	12000000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - HWL Holdings, LLC (058630887)

Establishment

Name	Address	ID/FEI	Business Operations
HWL Holdings, LLC		058630887	manufacture(75446-222)

Revised: 4/2020 HWL Holdings, LLC