WATERLESS ALCOHOL HAND SANITIZER GEL- waterless alcohol hand sanitizer gel gel Jiangsu Manwei Pharmaceutical Co.,Ltd

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.

Waterless Alcohol Hand Sanitizer Gel

Active Ingredient

Ethanol 75%(V/V)

Purpose

Disinfectant

Uses

Can kill bacteria on hands suchas: Escherichia coli, Staphylococcus aureusCandida albicans

Warnings

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

When using this product

When using this product]do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water Stop use and ask doctor if irritation or rash appears and lasts. Keep out of reach for children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough Product in your palm to thoroughly spread on both hands and rub into the skin until dry
- Children under 6 years of age should be supervised when using this product

Other information

Store in a cool and ventilated place under 22 C

Inactive ingredients

Weter Carbomer Triethanolamine



WATERLESS ALCOHOL HAND SANITIZER GEL

waterless alcohol hand sanitizer gel gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:75086-009 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER 934 (UNII: Z135WT9208)		
TROLAMINE (UNII: 9O3K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75086-009-01	8 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75086-009- 02	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75086-009-	15 ml in 1 ROTTI F. Tune O. Not a Combination Product	0.4/20./20.20	

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4	NDC:75086-009- 04	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
5	NDC:75086-009- 05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
6	NDC:75086-009- 06	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
7	NDC:75086-009- 07	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
8	NDC:75086-009- 08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
9	NDC:75086-009- 09	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
10	NDC:75086-009-10	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
11	NDC:75086-009-11	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
12	NDC:75086-009-12	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	
13	NDC:75086-009-13	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/20/2020		

Labeler - Jiangsu Manwei Pharmaceutical Co.,Ltd (554529430)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jiangsu Manwei Pharmaceutical Co.,Ltd		554529430	manufacture(75086-009)	

Revised: 4/2020 Jiangsu Manwei Pharmaceutical Co.,Ltd