## VITALSAIL- alcohol gel MEY SEE 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.

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## Vitalsail Alcohol Antiseptic 75% Gel

#### Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

#### Purpose

Antiseptic, Hand Sanitizer

#### Use

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

#### Warnings

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

## Inactive ingredients

Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked), Poloxamer 407, Sodium Hyaluronate,

Aloe, Polyoxyl 40 Hydrogenated Castor Oil, Alpha-Tocopherol Acetate, Purified Water

#### Label



## 500ml NDC:75813-102-01



VITALSAIL alcohol gel							
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:75813-102			
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredient Name			Basis of Strength		Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	75	5 mL in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
poloxamer 407 (UNII: TUF2IVW3M2)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
aloe (UNII: V5VD430 YW9)	
polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
water (UNII: 059QF0KO0R)	

Packaging								
#	Item Code		Package Description	Marketing Start Date	Marketing End Date			
1	NDC:75813-102- 01	500 m Produ	nL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	06/22/2020				
2	NDC:75813-102- 02	3785	mL in 1 PACKAGE; Type 0: Not a Combination Product	06/22/2020				
Marketing Information								
	Marketing Categ		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	TC monograph not	final	part333A	06/22/2020				

Labeler - MEY SEE PHARMACEUTICAL CO., LTD. (656348307)

**Registrant -** MEY SEE PHARMACEUTICAL CO., LTD. (656348307)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
MEY SEE PHARMACEUTICAL CO., LT D.		656348307	manufacture(75813-102)

Revised: 6/2020

MEY SEE PHARMACEUTICAL CO., LTD.