

WASH-FREE SURGICAL HAND DISINFECTANT GEL II- ethanol gel **Shan Dong Lircon Medical Technology 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.

SPL file for drug listing

Disinfectant type

Antiseptic, Hand Sanitizer

Major ingredient and concentration

This product is a disinfectant gel with ethanol as the main active ingredient, and the ethanol content is 75%±7.5% v/v. Add skin care ingredients such as moisturizers and moisturizers.

Germicidal spectrum

Antiseptic, Hand Sanitizer. It can kill the microorganisms such as enteric pathogenic bacteria, pyogenic coccus, pathogenic yeast and hospital infection common germs.

Application scope

1. Sanitary hand disinfection: suitable for hand disinfection of medical staff in outpatient clinics, wards, emergency room, intensive care units, hemodialysis rooms, and endoscopy rooms of medical and health institutions. It is suitable for quick disinfection of hands of persons who need to perform hand hygiene.
2. Surgical hand disinfection: suitable for preoperative surgical hand disinfection in the operating room of medical and health institutions.

Cautions

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.

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.

Usage

Sanitary hand disinfection: Take an appropriate amount of disinfectant gel (2-3ml) on the palm, rub your hands together to make it evenly spread on each part (ensure that the liquid covers the entire surface), Follow the WS/T313 "Specification of hand hygiene for health care workers

" Appendix A, the method of hand washing for medical workers, rub and disinfect for 1 minute.

Surgical hand disinfection 1. Wash hands and forearms, rinse thoroughly and dry. 2.

Take an appropriate amount of disinfectant gel (5-10ml), follow the WS/T313

"Specification of hand hygiene for health care workers " Appendix C Surgical no-wash disinfection method, rub your hands and forearms to the lower third of the upper arms for 3 minutes. Wear sterile gloves after drying.

Other information

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

carbomer, triethanolamine, glycerol, purified water.

package

package label is attached

Proprietary Name
 Wash-Free Surgical Hand
 Disinfectant Gel II
 Topical Gel

Hand Sanitizer
 Non-sterile Gel

60 mL

NDC: 81630-002-01

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 64.8% v/v	Antiseptic
Uses[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81630-002
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	64.8 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.3 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
WATER (UNII: 059QF0KO0R)	32.8 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81630-002-03	10 in 1 BOX	03/31/2021	
1	NDC:81630-002-02	10 in 1 BOX		
1	NDC:81630-002-01	60 mL in 1 BOTTLE, PLASTIC; Number of Units = ; Type 0: Not a Combination Product		
2	NDC:81630-002-05	40 in 1 BOX	03/31/2021	
2	NDC:81630-002-04	248 mL in 1 BOTTLE, PLASTIC; Number of Units = ; Type 0: Not a Combination Product		
3	NDC:81630-002-07	25 in 1 BOX	03/31/2021	
3	NDC:81630-002-06	500 mL in 1 BOTTLE, PLASTIC; Number of Units = ; Type 0: Not a Combination Product		
4	NDC:81630-002-09	16 in 1 BOX	03/31/2021	
4	NDC:81630-002-08	1000 mL in 1 BOTTLE, PLASTIC; Number of Units = ; Type 0: Not a Combination Product		
5	NDC:81630-002-11	15 in 1 BOX	03/31/2021	
5	NDC:81630-002-10	1000 mL in 1 BOTTLE, PLASTIC; Number of Units = ; Type 0: Not a Combination Product		
6	NDC:81630-002-13	5 in 1 BOX	03/31/2021	
6	NDC:81630-002-12	5000 mL in 1 PACKAGE; Number of Units = ; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2021	

Labeler - Shan Dong Lircon Medical Technology Co., Ltd (529169607)

Registrant - Shan Dong Lircon Medical Technology Co., Ltd (529169607)

Establishment

Name	Address	ID/FEI	Business Operations
Shan Dong Lircon Medical Technology Co., Ltd		529169607	manufacture(81630-002)

Revised: 3/2021

Shan Dong Lircon Medical Technology Co., Ltd