

# **QUICK-DRYING RINSE-FREE HAND SKIN DISINFECTANT- quick-drying rinse-free hand skin disinfectant gel**

**Shandong Kehong 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.*

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## **Quick-drying rinse-free hand&skin disinfectant**

### **Active Ingredients**

Chlorohexidine gluconate 1.0% w/v

Ethanol 75.0% v/v

### **Purpose**

Antimicrobial

### **Uses**

Quick-drying rinse-free hand skin disinfectant to disinfect surgical hand, hygienic hand and intact skin

### **Warnings**

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

### **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. Do not use on open skin wounds and people who are allergic to chlorohexidine and ethanol. Keep out of reach for children. If swallowed, get medical help right away

### **Directions**

1. Surgical hand disinfection: After washing and drying your hands and forearms with soap, take 5 ml of this product and evenly rub it to your hands and forearms according to methods specified in <Technical specification for disinfection> for 3 minutes, then sterile gloves can be worn.
- 2, Hygienic hand disinfection: Wipe or spray your hands with this product and rub until dry, and disinfect for 1 minute
3. Intact skin disinfection before injection or infusion: wipe or spray directly on the site to be disinfected for 1-2 times, sterilize for more than 1 minute
- 4 Before the operation, intact skin disinfection of the surgical site was carried out: preoperative preparation was carried out according to the standard requirements. The skin of the surgical site was evenly coated with this product with sterile gauze for 2 times or directly sprayed with the product for 2 times on the site to be disinfected for 2-3 minutes

### **Other information**

Sealed and stored in a cool, ventilated and dry place

### **Inactive ingredients**

Water(Aqua), Glycerol, Aloe extract

## Packaging Labels - Main Display Panel

QUICK-DRYING RINSE-FREE HAND SKIN DISINFECTANT			
quick-drying rinse-free hand skin disinfectant gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75244-005
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8 E) (CHLORHEXIDINE - UNII:R4K00DY52L)		CHLORHEXIDINE GLUCONATE	1g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	75 mL in 100 mL
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>		<b>Strength</b>	
WATER (UNII: 059QF0K00R)			
GLYCERIN (UNII: PDC6A3C0OX)			

ALOE VERA LEAF (UNII: ZY81Z83H0X)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75244-005-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
2	NDC:75244-005-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
3	NDC:75244-005-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
4	NDC:75244-005-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
5	NDC:75244-005-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
6	NDC:75244-005-06	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
7	NDC:75244-005-07	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	
8	NDC:75244-005-08	1000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/29/2020	

**Labeler** - Shandong Kehong Medical Technology Co.,Ltd. (554527496)

### Establishment

Name	Address	ID/FEI	Business Operations
Shandong Kehong Medical Technology Co.,Ltd		554527496	manufacture(75244-005)

Revised: 4/2020

Shandong Kehong Medical Technology Co.,Ltd.