

MEDITIME HAND SANITIZING- alcohol gel

Icure Pharmaceutical Inc, Wanju Factory

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.

Active Ingredients

Active ingredients: Alcohol 70% v/v

INACTIVE INGREDIENT

Inactive ingredients:

Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerine, Isopropyl Myristate, Tocopheryl Acetate, Aloe Barbadosensis Leaf Juice, 1,2-Hexanediol, Mentha Piperita (Peppermint) Oil, Limonene

Purpose

Purpose: Antimicrobial

Warnings

Warnings:

For external use only. Flammable.

Keep away from heat or flame.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Uses:

Decrease bacteria on hands

Directions

Directions:

Wet hands thoroughly with product and allow to dry.

Children under 6 years of age, use only under adult supervision.


Other information

Other information:

Do not store above 105°(43°)

May discolor some fabrics and surfaces

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Hand Sanitizing Gel


With Moisturizers

Alcohol 70% v/v


Protects Skin Against Harmful Bacteria & Infection


Topical Soutlion

500ml / 16.90 fl.oz.



Aloe & Vitamin E






Drug Facts

Active Ingredient	Purpose
Alcohol 70% v/v	Antimicrobial
Uses ▶ Decreases bacteria on skin	
Warnings For external use only. Flammable. Keep away from heat or flame.	
When using this product , avoid contact with eyes. In case of contact flush eyes with water.	
Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours.	
Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ▶ Wet hands thoroughly with product and allow to dry. ▶ Children under 6 years of age, use only under adult supervision.	
Other Information ▶ Do not store above 105°F(43°C). ▶ May discolor some fabrics and surfaces.	
Inactive ingredients Water, Carbomer, Triethanolamine, Propylene Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, 1,2-Hexanediol, Mentha Piperita (Peppermint) Oil, *Limonene	
Distributed by : ICURE Pharmaceutical INC. 248, Wanjusandan 5-ro, Bongdong-eup, Wanju-gun, Jeollabuk-do, Republic of Korea	

ICURE PHARMACEUTICAL INC.
www.meditime.com
MADE IN KOREA



MEDITIME HAND SANITIZING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73279-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

1,2-Hexanediol (UNII: TR046Y3K1G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73279-0002-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Registrant - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Establishment

Name	Address	ID/FEI	Business Operations
Icure Pharmaceutical Inc, Wanju Factory		695687612	manufacture(73279-0002)

Revised: 4/2020

Icure Pharmaceutical Inc, Wanju Factory