## RUBBING ALCOHOL- alcohol liquid INTERNATIONAL GENERAL TRADING CORP

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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#### **RUBBIN ALCOHOL 50%**

#### **Active Ingredient(s)**

Isopropyl Alcohol 50% v/v. Purpose: Antiseptic

#### **Purpose**

aNTIMICROBIAL

#### Use

DECREASE GERMS IN MINOR CUTS AND HELPS RELIEVE MINO MUSCULAR ACHES DUE TO EXERTION

#### 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.

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#### **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**

WATER

#### Package Label - Principal Display Panel

Size: 45 x 115 mm



354 ML

#### **RUBBING ALCOHOL**

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78440-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL UNII: ND2M416302)	- ISOPROPYL ALCOHOL	50 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78440-009- 01	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2021	

# Size: 45 x 115 mm

ALCO	50% ISOPROPYL BBING HOL
Drug Facts Active Ingrdient (by volume)	Purpose
Isopropyl alcohol (50% concentrate)	topical antimicrobial
Uses • to decrease germs in minor cuts • helps relieve minor muscular aches d	
Warnings • For external use only • flammable, keep away from fire and t • will produce serious gastric disturbar	
Ask a doctor before use if you have of serious burns	deep puncture wounds or
When using this product • do not get membranes • use only in a well-ventile	
Stop use and ask a doctor if condition	100000000000000000000000000000000000000

Keep out of reach of children. In case of an accidental ingestion, contact a Poison Control Center immediately. Directions - apply to skin directly of with clean gauze, cotton or swab - for rubbing, apply liberally and rub with hands Other Information - does not contain, nor is intended as a substitute for grain or ethyl alcohol - keep bottle tightly closed Inactive Ingredient: Water MADE IN INDIA DISTRIBUTED BY: IGT CORP, NEW YORK, NY 10018 12 FL 0Z (354 mL)

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/12/2021	

### Labeler - INTERNATIONAL GENERAL TRADING CORP (825499598)

## Registrant - International General Trading Corp (825499598)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
JELL PHARMACEUTICALS PRIVATE LIMITED		726025211	manufacture(78440-009)