ISOPROPYL RUBBING ALCOHOL 70% WITH WINTERGREEN- is opropyl alcohol liquid Singhfam Corporation

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.

ISOPROPYL RUBBING ALCOHOL 70% WITH WINTERGREEN

Active ingredients (by volume)

Isopropyl alcohol (70% conc.)

Purpose

first aid antiseptic

Uses

• first aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings

For external use only; flammable, keep away from fire or flame, heat, spark, electrical.

Ask a doctor before use if you have

• deep punctured wounds, animal bites or serious burns

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than one week unless directed by a doctor

Stop using this product if

condition persists or gets worse

Keep this and all drugs out of the reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison control center (1-800-222-1212) immediately

Directions

- clean effected area
- apply small amount of this product on the area 1-3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first

Other information

- store at room temperature
- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric disturbance if taken internally

Inactive Ingredients

Water(Aqua), Methyl Salicylate, FD&C Blue #1, FD&C Yellow #5

PRINCIPAL DISPLAY PANEL

ISOPROPYL RUBBING ALCOHOL 70% WITH WINTERGREEN

FIRST AID ANTISEPTIC





lsopropyl rubbing alcohol 70% by volume

Drug Facts

Active ingredients (by volume):

Purpose

Isopropyl alcohol

(70% conc.) first aid antiseptic

Uses ■ first aid to help prevent the risk of infection in minor cuts, scrapes and burns

Warnings

For external use only; flammable, keep away from fire or flame, heat, spark, electrical

Ask a doctor before use if you have

deep punctured wounds, animal bites or serious burns

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than one week unless directed by a doctor

Stop using this product if

condition persists or gets worse

Keep this and all drugs out of the reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison control center (1-800-222-1222) immediately.

Directions

- clean effected area
- apply small amount of this product on the area 1-3 times daily
- May be covered with a sterile bandage
- If bandaged, let dry first

Other information

- store at room temperature
- does not contain, nor is intended as a substitute for grain or ethyl alcohol. will produce serious gastric disturbances if taken internally.

Inactive Ingredient Water(Aqua), Methyl Salicylate, F D&C Blue #1,FD &C Yellow #5.

TAMPER EVIDENT: DO NOT USE IF THE UNDER CAP SAFETY FOIL IS BROKEN OR MISSING.

8 WH/DB/NGS/KD-313

Made in India / Hecho en India
Dist. by: Singhfam Corporation
Port Washington, NY 11050
www.singhfam.com
www.elizabethstyleintl.com

isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52920-132	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52920-132- 41	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:52920-132- 42	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:52920-132- 43	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:52920-132- 44	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:52920-132- 45	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:52920-132- 46	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:52920-132- 47	473 mL in 1 BOTTLE, PLASTIC; 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	08/10/2015		

Labeler - Singhfam Corporation (019499958)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52920-132)	

Revised: 8/2015 Singhfam Corporation