ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN OIL- isopropyl alcohol liquid Pioneer Associates

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.

CAVALIER ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN OIL

Active ingredient (by volume)

Isopropyl alcohol (50% conc.)

Purpose

first aid antiseptic

Uses

- first aid to help prevent risk of infection in:
- minor cuts
- scrapes
- burns

Warnings

For external use only

- flammable, keep away from fire and flame
- will produce serious gastric disturbances if taken internally

Ask a doctor before use if you have deep puncture wounds or serious burns

When using this product

- do not get into eyes or mucous membranes
- use in well-ventilated area: forms may be toxic

Stop use and ask a doctor if condition persists or gets worse

Keep out of reach of children.

In case of an accidental ingestion, contact a Poison Control Center immediately

Directions

- apply to skin directly or 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 (Agua), methyl salicylate, laneth-75, FD&C Blue #1, FD&C Yellow #5

PRINCIPAL DISPLAY PANEL

CAVALIER ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN OIL

FIRST AID ANTISEPTIC

12 FL.OZ (354 mL)



50% ISOPROPYL RUBBING ALCOHOL

with Wintergreen Oil

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DISTRIBUTED BY:

Pioneer Associates

Brooklyn, NY 11206 www.pioneermorton.com



Made in India

12 FL.OZ. (354mL)

ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN OIL

isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53033-002	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety				
l	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)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
PEG-75 LANOLIN (UNII: 09179 O X7TB)			
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:53033-002-01	119 mL in 1 BOTTLE, PLASTIC		
2	NDC:53033-002-02	178 mL in 1 BOTTLE, PLASTIC		
3	NDC:53033-002-03	237 mL in 1 BOTTLE, PLASTIC		
4	NDC:53033-002-04	295 mL in 1 BOTTLE, PLASTIC		
5	NDC:53033-002-05	354 mL in 1 BOTTLE, PLASTIC		
6	NDC:53033-002-06	414 mL in 1 BOTTLE, PLASTIC		
7	NDC:53033-002-07	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333A	08/24/2012		

Labeler - Pioneer Associates (012604336)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anicare Pharmaceuticals Pvt. Ltd		9 16 8 37 42 5	manufacture(53033-002)	

Revised: 8/2012 Pioneer Associates