# 50% ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN- is opropyl alcohol liquid AMERICAN CONSUMER PRODUCTS LLC

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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#### 50% Isopropyl Rubbing Alcohol with Wintergreen

#### **Active Ingredient (by volume)**

Isopropyl alcohol (50% conc.)

#### **Purpose**

Topical Antimicrobial

#### Uses

- decrease germs in minor cuts and scrapes.
- helps relieve minor muscular aches due to exertion.

#### 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 serious burns

#### When using this product

- do not get into eyes or mucous membranes
- use only in a well-ventilated area

**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 Ingredients**

Water (Aqua), Methyl Salicylate, Laneth-75, FD&C Blue #1, FD&C Yellow #5

#### PRINCIPAL DISPLAY PANEL

50% ISOPROPYL RUBBING ALCOHOL WITH WINTERGEEN

Topical Antimicrobial

12 FL.OZ (354 mL)



# 50% ISOPROPYL RUBBING ALCOHOL

with Wintergreen Oil

### **Drug Facts**

Active ingredient (by volume)

**Purpose** 

Isopropyl alcohol

(50% conc.)..... topical antimicrobial

**Uses** ☐ to decrease germs in minor cuts and scrapes.

☐ helps relieve minor muscular aches due to exertion.

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#### Directions

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 □ for rubbing, apply liberally and rub with hands.

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Inactive ingredient: Water (Aqua), Methyl Salicylate, Laneth-75,FD&C Blue#1, FD&C Yellow #5

DISTRIBUTED BY:

American Consumer Products, LLC LOS ANGELES, CA USA



Made in India

# 12 FL.OZ.354 ml

#### 50% ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN

isopropyl alcohol liquid

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:18027-003

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

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	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:18027-003- 01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
2 NDC:18027-003- 02	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
3 NDC:18027-003- 03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
4 NDC:18027-003- 04	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
5 NDC:18027-003- 05	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
6 NDC:18027-003- 06	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	
7 NDC:18027-003- 07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2017	

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	07/15/2017				

# Labeler - AMERICAN CONSUMER PRODUCTS LLC (858427334)

## Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(18027-003)	

Revised: 7/2017 AMERICAN CONSUMER PRODUCTS LLC