

**ISOPROPYL ALCOHOL- isopropyl alcohol solution**  
**Apotex Pharmachem Inc.**

*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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**Drug Facts**

**Active ingredient(s)**

Isopropyl Alcohol Antiseptic 75% Topical Solution, Hand Sanitizer Non-Sterile Solution

**Purpose**

Antiseptic

**Use(s)**

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only. Keep away from open flame and sources of heat.

**Do not use**

Do not use on children less than 2 months old.

Do not use on open skin wounds.

**Ask a doctor before use if**

Information required in 201.66(c)(5)(iv)

**Ask a doctor or pharmacist before use if**

Information required in 201.66(c)(5)(v)

**When using this product**

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 doctor if**

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

**Other required warnings**

Information required in 201.66 (c)(5)(viii)

**Pregnancy/Breastfeeding**

Information required in 201.66(c)(5)(ix)

**Keep out of reach of children**

Keep out of reach of children, if swallowed, call a poison control center right away.

### 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)

### Storage

Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, water

### Questions

Questions? 1-800-667-4708 or 1-416-401-7780 (follow prompts)

Report adverse reactions to the above numbers or [drugsafety@apotex.com](mailto:drugsafety@apotex.com)

### Principal Display Panel

Representative sample of labeling: PRINCIPAL DISPLAY PANEL - DRUM LABEL ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION, HAND SANITIZER NON-STERILE SOLUTION: HANDLING UNIT #: NDC 49867-0072-0: BATCH NUMBER.: GROSS WT.: MFG. DATE: TARE WT.: RETEST DATE: NET WT.: CONTAINER NO.: STORAGE CONDITION: STORE BETWEEN 15-30C (59-86F): TRANSPORTATION CONDITION: AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F): LABEL SERIAL #: MANUFACTURED BY APOTEX PHARMACHEM INC.: MADE IN: CANADA

## Isopropyl Alcohol Antiseptic 75% Topical Solution, Hand Sanitizer Non-Sterile Solution

Handling Unit#	:	NDC#	:	49867-0072-0
Batch Number	:	Gross Wt:	:	
Mfg. Date	:	Tare Wt :	:	
Retest Date	:	Net Wt :	:	
Container No.	:			

**Storage Condition:** Store between 15 - 30C (59 - 86F).

**Transportation Condition:** Avoid freezing and excessive heat above 40C (104F).

Label Serial #:

Manufactured by:

Made in: Canada



# **A** APOTEX PHARMACHEM INC.

34, 50 Spalding Drive, Brantford, Ontario, Canada, N3T 6B8

## **ISOPROPYL ALCOHOL**

isopropyl alcohol solution

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49867-0072
<b>Route of Administration</b>	TOPICAL		

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

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Isopropyl Alcohol</b> (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	750 g in 1 kg

**Inactive Ingredients**

Ingredient Name	Strength
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Hydrogen Peroxide</b> (UNII: BBX060AN9V)	
<b>Water</b> (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49867-0072-0	208 kg in 1 DRUM; Type 0: Not a Combination Product	04/13/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

**Labeler** - Apotex Pharmachem Inc. (209840537)

Revised: 4/2020

Apotex Pharmachem Inc.