

## **HAND SANITIZER- isopropyl alcohol solution**

**Alcon Laboratories, 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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### **HAND SANITIZER**

#### ***Drug Facts***

##### ***Active Ingredient***

Isopropyl Alcohol Antiseptic 75%

##### ***Purpose***

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

##### ***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.

##### ***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 below 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

##### ***Inactive Ingredients***

glycerin, hydrogen peroxide, purified water USP

##### ***Questions?***

In the U.S., call 1-800-757-9195 or email [alcon.medinfo@alcon.com](mailto:alcon.medinfo@alcon.com)

**PACKAGE LABEL**

**NOT FOR SALE**

NDC: 0065-9800-01

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Hand Sanitizer**

**Non-sterile Solution**

**10,000 mL Fill Volume**

**Alcon**

Alcon Laboratories, Inc.  
Fort Worth, TX 76134

LOT:            EXP:

PN: 1-2222222222

**NOT FOR SALE**  
NDC: 0065-9800-01

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Hand Sanitizer**

**Non-sterile Solution**

**10,000 mL Fill Volume**

**Alcon**

Alcon Laboratories, Inc.  
Fort Worth, TX 76134

LOT:            EXP:

PN: 1-222222222a

**Drug Facts**

**Active ingredient**

Isopropyl Alcohol 75%v/v

**Purpose**

Antiseptic

**Use**

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

**Warnings**

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**Questions?**

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PN 2-22222222a

**NOT FOR SALE**  
NDC: 0065-9800-02

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub**

**Non-sterile Solution**

**10,000 mL Fill Volume**

**Alcon**

Alcon Laboratories, Inc.  
Fort Worth, TX 76134

LOT:            EXP:

PN: 1-111111111

**NOT FOR SALE**  
NDC: 0065-9800-02

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub**

**Non-sterile Solution**

**10,000 mL Fill Volume**

**Alcon**

Alcon Laboratories, Inc.  
Fort Worth, TX 76134

LOT:            EXP:

PN: 1-111111111a

**Drug Facts**

**Active ingredient**

Isopropyl Alcohol 75%v/v

**Purpose**

Antiseptic

**Use**

Health care personnel hand rub to help reduce bacteria that can potentially cause disease.

**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.

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PN: 2-111111111a

**HAND SANITIZER**

isopropyl alcohol solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0065-9800
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>Isopropyl Alcohol</b> (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Hydrogen Peroxide</b> (UNII: BBX060AN9V)	
<b>Water</b> (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-9800-01	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
2	NDC:0065-9800-02	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
3	NDC:0065-9800-05	19000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
4	NDC:0065-9800-06	19000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	
5	NDC:0065-9800-07	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

**Labeler** - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-9800)

Revised: 4/2020

Alcon Laboratories, Inc.