CAREPURE 01- isopropyl alcohol liquid Carestream Health, 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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. 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.

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.

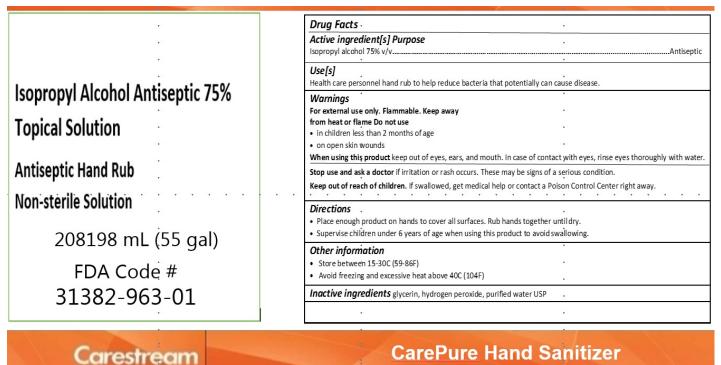
Other information

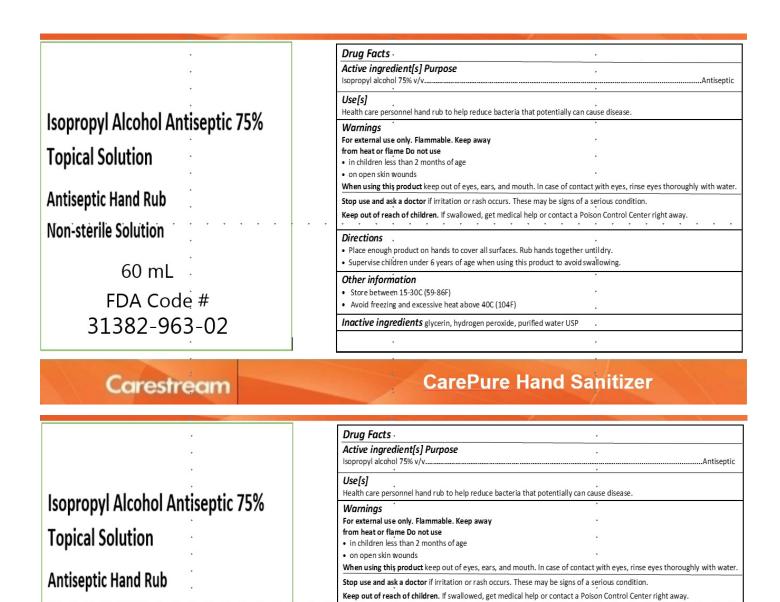
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel





Directions

Other information
• Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

31382-963-03

80 mL

FDA Code #

Non-sterile Solution

Carestream

CarePure Hand Sanitizer

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

•	Drug Facts .
	Active ingredient[s] Purpose
	Isopropyl alcohol 75% v/vAntiseptic
	Use[s]
	Health care personnel hand rub to help reduce bacteria that potentially can cause disease.
Isopropyl Alcohol Antiseptic 75%	Warnings
· · · ·	For external use only. Flammable. Keep away
Topical Solution	from heat or flame Do not use
ropical solution	in children less than 2 months of age on open skin wounds
	 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.
Antiseptic Hand Rub	Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Antiseptic Italia Nas	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Non-sterile Solution	
Non-sterne solution	Directions .
	Place enough product on hands to cover all surfaces. Rub hands together until dry.
120 mL	 Supervise children under 6 years of age when using this product to avoid swallowing.
	Other information
FDA Code #	Store between 15-30C (59-86F)
FDA Code #	Avoid freezing and excessive heat above 40C (104F)
31382-963-04	Inactive ingredients glycerin, hydrogen peroxide, purified water USP .
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Carestream	CarePure Hand Sanitizer
Carestream	

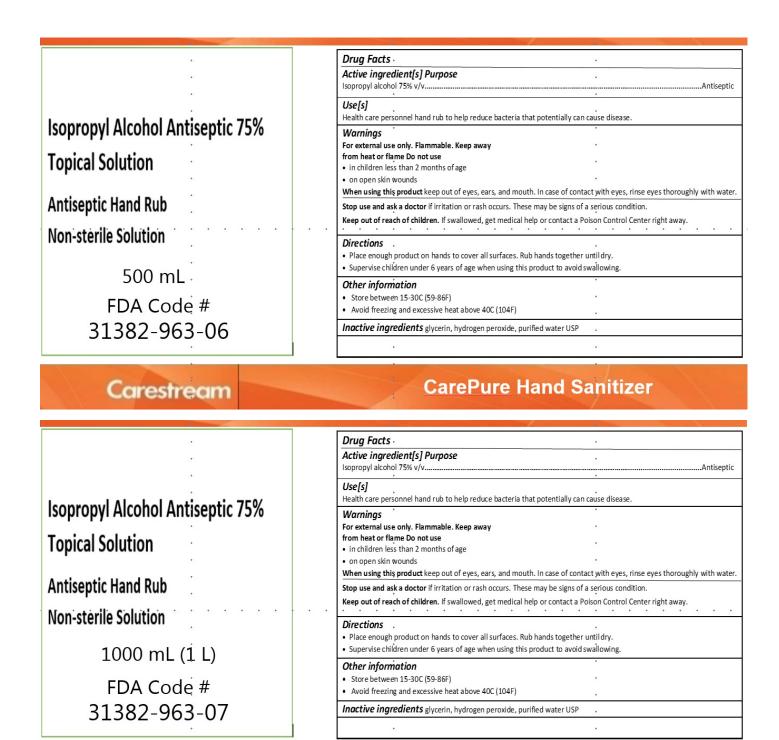
Drug Facts

Use[s]
Health careIsopropyl Alcohol Antiseptic 75%Topical SolutionAntiseptic Hand RubNon-sterile Solution240 mL (80z)FDA Code #
31382-963-05Isopropyl Alcohol Antiseptic Hand Rub

Active ingredient[s] Purpose Isopropyl alcohol 75% v/v. Antiseptic Health care personnel hand rub to help reduce bacteria that potentially can 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. 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 between 15-30C (59-86F) · Avoid freezing and excessive heat above 40C (104F) Inactive ingredients glycerin, hydrogen peroxide, purified water USP .

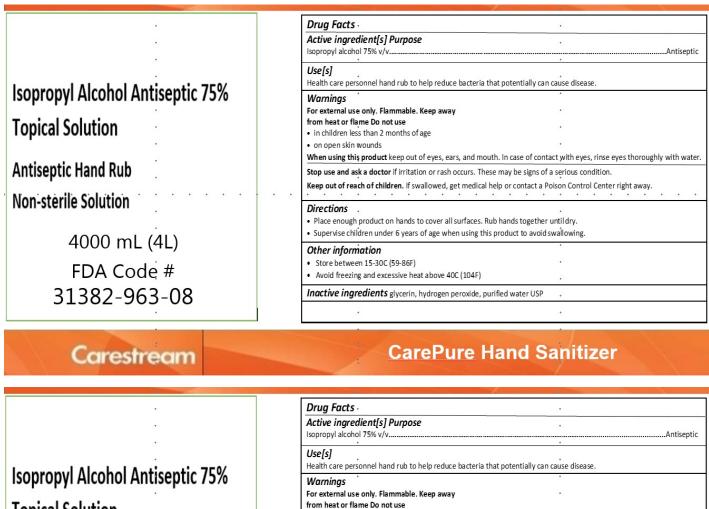
Carestream

CarePure Hand Sanitizer



Carestream

CarePure Hand Sanitizer



in children less than 2 months of age

Avoid freezing and excessive heat above 40C (104F)

on open skin wounds

Other information
• Store between 15-30C (59-86F)

Directions

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution 5000 mL (5 L)

> FDA Code # 31382-963-09

> > Carestream

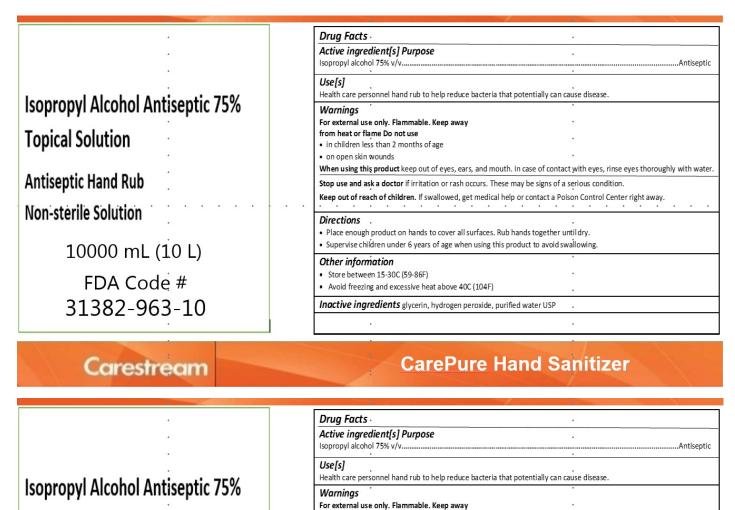
CarePure Hand Sanitizer

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

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.

Inactive ingredients glycerin, hydrogen peroxide, purified water USP



from heat or flame Do not use • in children less than 2 months of age

on open skin wounds

Other information
• Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Directions

Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

7571 mL (2 gal) FDA Code # 31382-963-11

Carestream

CarePure Hand Sanitizer

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.

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

•	Drug Facts .
*	Active ingredient[s] Purpose
•	Isopropyl alcohol 75% v/vAntiseptic
	Use[s]
leannand Alashal Anticantia 750/	Health care personnel hand rub to help reduce bacteria that potentially can cause disease.
Isopropyl Alcohol Antiseptic 75%	Warnings
- · · · ·	For external use only. Flammable. Keep away
Topical Solution	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.
Antiseptic Hand Rub	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.
Non-sterile Solution	Directions
•	 Place enough product on hands to cover all surfaces. Rub hands together until dry.
10007 mal (F mal)	Supervise children under 6 years of age when using this product to avoid swallowing.
18927 mL (5 gal)	Other information
FDA Code #	Store between 15-30C (59-86F)
FDA COUR #	Avoid freezing and excessive heat above 40C (104F)
31382-963-12	Inactive ingredients glycerin, hydrogen peroxide, purified water USP .
51502 505 12	
Carestream	CarePure Hand Sanitizer
Con Con Con Con II	

· · · · · · · · · · · · · · · · · · ·	Drug Facts Active ingredient[s] Purpose Isopropyl alcohol 75% v/vAntiseptic		
Isopropyl Alcohol Antiseptic 75%	Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease. Warnings		
Topical Solution	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. 		
Antiseptic Hand Rub	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.		
Non-sterile Solution	Directions . • Place enough product on hands to cover all surfaces. Rub hands together until dry.		
250 mL	Supervise children under 6 years of age when using this product to avoid swallowing. Other information		
FDA Code #	Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)		
31382-963-13	Inactive ingredients glycerin, hydrogen peroxide, purified water USP .		

Carestream

CarePure Hand Sanitizer

CAREPURE 01						
isopropyl alcohol liquid						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31382-963			
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						

		Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)				ISOPROPYL Alcohol	75 mL in 100 mL
In	active Ingredi	ents			
		Ingredient Name		Strer	ıgth
GI	GLYCERIN (UNII: PDC6A3C0OX) 0.725 mL in 100 ml			$0.725 \; mL \;$ in 100 mL	
Щ	YDROGEN PEROXIDE (UNII: BBX060AN9V)0.125 mL in 100 mL				
W	ATER (UNII: 059QF	0KO0R)			
Pa	ackaging				
Ра #	ackaging Item Code	Package Description	Maı	rketing Start M Date	Marketing End Date
		Package Description 208198 mL in 1 DRUM; Type 0: Not a Combination Product	Mai 03/30/2	Date	0
#	Item Code NDC:31382-963-			Date 20 20	0
# 1	Item Code NDC:31382-963- 01 NDC:31382-963-	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/	Date 20 20 20 20	0
# 1 2	Item Code NDC:31382-963- 01 NDC:31382-963- 02 NDC:31382-963-	208198 mL in 1 DRUM; Type 0: Not a Combination Product 60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2	Date 20 20 20 20 20 20	Marketing End Date

4	NDC:31382-963- 04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:31382-963- 05	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:31382-963- 06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:31382-963- 07	1000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
8	NDC:31382-963- 08	4000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
9	NDC:31382-963- 09	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
10	NDC:31382-963- 10	10000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
11	NDC:31382-963- 11	7571 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
12	NDC:31382-963- 12	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
13	NDC:31382-963- 13	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Carestream Health, Inc. (793169512)