

GUARDEX PHARMA HAND SANITIZER- isopropyl alcohol 75% liquid
21st Century Chemical, 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.

Guardex Pharma Hand Sanitizer

Active Ingredient

Isopropyl Alcohol 75%

Purpose

Antiseptic

Uses

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

On 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

Guardex Pharma Hand Sanitizer



Clean Hands Start Here.

Drug Facts	
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Dania Beach FL 33312



For more information please visit www.guardexlabs.com

GUARDEX PHARMA HAND SANITIZER

isopropyl alcohol 75% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77390-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	2839 mL in 3785 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77390-101-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - 21st Century Chemical, Inc. (037798686)

Registrant - 21st Century Chemical, Inc. (037798686)

Revised: 8/2020

21st Century Chemical, Inc.