ISOPROPYL ALCOHOL ANTISEPTIC 75% - isopropyl alcohol antiseptic 75 % solution Aurohealth 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.

Is opropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub

ACTIVE INGREDIENT(S)

Isopropyl alcohol 75% v/v

PURPOSE

Antiseptic

USE(S)

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

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.

KEEP OUT OF REACH OF CHILDREN

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 15-30^oC (59-86^oF)

• Avoid freezing and excessive heat about 40^oC (104^oF)

INACTIVE INGREDIENT SECTION

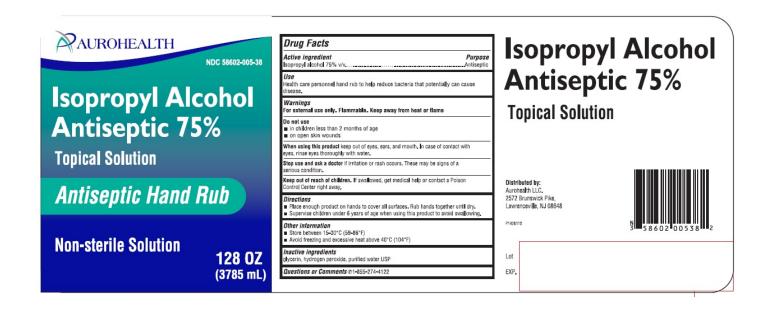
Glycerin, hydrogen peroxide, purified water USP

QUESTIONS OR COMMENTS

1-855-274-422

PRINCIPAL DISPLAY PANEL

NDC 58602-005-38 Isopropyl Alcohol Antiseptic 75% Topical Solution Antiseptic Hand Rub Non-sterile Solution 128 OZ (3785mL)



ISOPROPYL ALCOHOL ANTISEPTIC 75%

isopropyl alcohol antiseptic 75 % solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-005
Route of Administration	TOPICAL		

f Strength	Strength
	75 mL in 100 mL
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Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6 A3C0 OX)		
HYDRO GEN PERO XIDE (UNII: BBX060 AN9 V)		
WATER (UNII: 059QF0KO0R)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:58602-005-38	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	06/25/2020	

Labeler - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurolife Pharma LLC		080970299	ANALYSIS(58602-005), RELABEL(58602-005), REPACK(58602-005), LABEL(58602-005), MANUFACTURE(58602-005), PACK(58602-005)

Revised: 6/2020 Aurohealth LLC