

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.

Isopropyl 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 15-30⁰C (59-86⁰F)

- Avoid freezing and excessive heat about 40⁰C (104⁰F)

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)



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Drug Facts

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When using this product

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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 8 years of age when using this product to avoid swallowing.

Other information

■ Store between 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 or Comments

©1-855-274-4122

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Distributed by:
AuroHealth LLC
2572 Brunswick Pike,
Lawrenceville, NJ 08648



58602005382

P1428110

Lot

EXP.

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		
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

Inactive Ingredients				
Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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
Auro life Pharma LLC		080970299	ANALYSIS(58602-005) , RELABEL(58602-005) , REPACK(58602-005) , LABEL(58602-005) , MANUFACTURE(58602-005) , PACK(58602-005)