

## **ALCOHOL ANTISEPTIC 80% - alcohol antiseptic 80% 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.*

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### **Alcohol Antiseptic 80% Topical Solution**

#### **Antiseptic Hand Rub**

#### **ACTIVE INGREDIENT(S)**

Alcohol 80% v/v

#### **PURPOSE**

Antiseptic

#### **USE(S)**

Health care personnel hand rub to help reduce bacteria that potentially causes 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 thoroughly with water.

#### **STOP USE AND ASK DOCTOR IF**

Stop using and ask 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°C (59-86°F)

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

## INACTIVE INGREDIENT SECTION

glycerin, hydrogen peroxide, purified water USP

## QUESTIONS OR COMMENTS

Call 1-855-274-4122

## PRINCIPAL DISPLAY PANEL

AUROHEALTH  
 NDC 58602-004-38  
 Alcohol Antiseptic 80%  
 Topical Solution  
 Antiseptic Hand Rub  
 Non-sterile Solution  
 128 OZ (3785 mL)

**Alcohol Antiseptic 80% Topical Solution**  
**Antiseptic Hand Rub**  
 Non-sterile Solution 128 OZ (3785 mL)

**Drug Facts**

<b>Active ingredient</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Use</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 8 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 15-30°C (59-86°F)</li> <li>Avoid freezing and excessive heat above 40°C (104°F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	
<b>Questions or Comments</b> ☎1-855-274-4122	

**Alcohol Antiseptic 80% Topical Solution**

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

58602-00438-5

Lot  
 EXP.

## ALCOHOL ANTISEPTIC 80%

alcohol antiseptic 80% solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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:58602-004-38	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(58602-004) , RELABEL(58602-004) , REPACK(58602-004) , LABEL(58602-004) , MANUFACTURE(58602-004) , PACK(58602-004)

Revised: 6/2020

Aurohealth LLC