

ALCOHOL ANTISEPTIC - alcohol solution

Natureplex 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.

ALCOHOL ANTISEPTIC 80%

Topical

Drug Facts

Active ingredient[s]

Alcohol 80% v/v

Purpose

Antiseptic

Use[s]

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.

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

PRINCIPAL DISPLAY PANEL - 3785.41 mL Jug Label

Natureplex Alcohol Antiseptic 80%
Topical Solution
NDC 67234-075-01

Hand Sanitizer
Non-sterile Solution

Natureplex, LLC
11085 Airport Rd Olive Branch, MS 38654
1-866-323-0107

Lot: XXXX
Part No: 3147

NATUREPLEX

1 gallon (3785.41 mL)

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ALCOHOL ANTISEPTIC

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-075
Route of Administration	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:67234-075-01	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	03/27/2020	
2	NDC:67234-075-02	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	03/27/2020	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-075)

Revised: 4/2020

Natureplex LLC