

**ETHYL ALCOHOL 80 PERCENT- ethyl alcohol liquid
CLUB CARIBE**

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.

ETHYL ALCOHOL 80 PERCENT

DOSAGE & ADMINISTRATION - ETHYL ALCOHOL 80% ANTISEPTIC

**Ethyl Alcohol 80% (As determined by DMA)
750 ml. (0.75 L.)
DO NOT CONSUME**

Drug Facts	
Active Ingredient[s]	Purpose
Denatured Ethyl Alcohol 80% v/v.....	Antiseptic
Use[s]	
First aid to help prevent the risk of infection in minor cuts, scrapes and burns	
Warnings	
For external use only	
<ul style="list-style-type: none">• Flammable, Keep away from heat or flame.• If taken internally serious gastric disturbances will result	
Ask a doctor before if you have	
<ul style="list-style-type: none">• deep or puncture wounds, animal bites or serious burns	
When using this product	
<ul style="list-style-type: none">• do not apply over large areas of the body• do not use longer than 1 week unless directed by a doctor	
Stop use and ask a doctor if condition persist or gets worse	
Keep out of reach of children . If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions	
<ul style="list-style-type: none">• clean affected area• apply a small amount of this product on the area 1-3 times daily• if bandaged, let dry first• may be covered with a sterile bandage	
Other information	
<ul style="list-style-type: none">• Store at room temperature	
Inactive ingredients: purified water, denatonium benzoate, tert-butyl alcohol	

Manufactured by: Bearco, LLC Carr. 172 Km 9.1 Cidra, P.R. 00739
Tel:787-739-7100 customer@bearcopr.com



WARNINGS - ETHYL ALCOHOL 80% ANTISEPTIC

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INDICATION & USAGE - ETHYL ALCOHOL 80% ANTISEPTIC

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KEEP OUT REACH CHILDREN - ETHYL ALCOHOL 80% ANTISEPTIC

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Use[s]	
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bums

Warnings

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- If taken Internally serious gastric disturbances will result

Ask a doctor before if you have

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ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74336-800
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
WATER (UNII: 059QF0KO0R)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74336-800-01	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - CLUB CARIBE (117033117)**Registrant** - CLUB CARIBE (117033117)**Establishment**

Name	Address	ID/FEI	Business Operations
CLUB CARIBE		117033117	manufacture(74336-800)

Revised: 6/2020

CLUB CARIBE