

ETHANOL- ethanol liquid
Golden Leaf Energy

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.

Active ingredient - Ethanol

Ethanol

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 96%.....	Antiseptic

Uses:

- To decrease bacteria on the skin that could cause disease
- Recommended for repeated use

Warnings:

- For external use only/topical use only
- Flammable, keep away from fire or flame

When using this product:

- Keep out of eyes, in case of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin
- Do not inhale or ingest

Stop use and ask a doctor if:

- Irritation and redness develop
- Condition persists for more than 72 hours

Keep out of reach of children:

- If swallowed, get medical help or contact a poison control center right away

Directions:

- Not recommended for infants

Other information:

- Do not store above 105F
- May discolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients – Zero, Pure Alcohol

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Drug Facts - Indications and usage

Drug Facts - Purpose

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96% Ethanol – 1000L

- Ethanol

ETHANOL

ethanol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79137-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	1 L in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79137-001-01	1 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2020	

Labeler - Golden Leaf Energy (117535023)

Establishment

Name	Address	ID/FEI	Business Operations
Golden Leaf Energy		117535023	manufacture(79137-001)

Revised: 6/2020

Golden Leaf Energy