

GNA- alcohol gel
GREENSYS OF NORTH AMERICA 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.

Active Ingredient

Ethyl Alcohol 70% v/v.

Purpose

Antiseptic

Use

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 15-30⁰C (59-86⁰F)
- Avoid freezing and excessive heat above 40⁰C (104⁰F)

Inactive ingredients

Acrylate copolymer, glycerin, hydrogen peroxide, Triethanolamine , water.

Package Label - Principal Display Panel



**Alcohol Antiseptic 70%
Sanitizing Gel**
Antiseptic Hand Sanitizer Non-sterile Solution

Drug Facts	
Ethyl Alcohol 70% v/v	Antiseptic
Uses	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 Center right away.
Directions	Place enough product to cover all surfaces, rub hand together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.
Other Information	Store between 15-30 C (59-86F) Avoid Freezing and excessive heat above 40C (104F)
Inactive Ingredients	Acrylates copolymer, Glycerin, Hydrogen Peroxide, Triethanolamine, Water

Manufactured by :
Greensys of North America LLC
5001W. Military Hwy. STE 100.
McAllen, Texas USA 78503
Made in USA

Lot: _____
Expiration Date: _____


2 oz (60ml)

GNA
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76692-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76692-001-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
2	NDC:76692-001-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
3	NDC:76692-001-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
4	NDC:76692-001-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
5	NDC:76692-001-05	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
6	NDC:76692-001-06	208198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
7	NDC:76692-001-07	1040990 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	
8	NDC:76692-001-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	06/05/2020	

Labeler - GREENSYS OF NORTH AMERICA LLC (075577393)

Establishment

Name	Address	ID/FEI	Business Operations
GREENSYS OF NORTH AMERICA LLC		075577393	manufacture(76692-001)

Revised: 6/2020

GREENSYS OF NORTH AMERICA LLC