

PYURX- ethanol alcohol gel
Novara 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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

See ingredients list for accurate list.

Active Ingredient(s)

Ethanol Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

- For hand washing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

- For external use only.
- Flammable. Keep away from heat or flame.

Do not use

- Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.
- Do not use on children less than 2 months of age.

Stop use and ask a doctor if

- Irritation and redness develop and persist for more than 72 hours.
 - Swallowed, get medical help or contact a poison control center right away.

Keep out of reach of children. Children must be supervised in use of this product.

Directions

- Place enough product in your palm to cover hands and rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110F (43C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Aqua(Water), Glycerin, Carbomer, Triethanolamine, Aloe, Tocopheryl Acetate (Vitamin E).

Package Label - Principal Display Panel

500ml. NDC: 80527-251-50



SANITIZER

LEAVES HANDS FEELING SOFT & REFRESHED
**VITAMIN E
+ ALOE
FORMULA**
LEAVES HANDS FEELING SOFT & REFRESHED

**HIGH
POTENCY**

KILLS 99.99% OF GERMS

**ANTI-BACTERIAL
75% ALCOHOL**

16.9 FL OZ | 500ml

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75% ALCOHOL**

KILLS 99.99% OF GERMS

Drug Facts

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Ethyl Alcohol 75% v/v	Antiseptic

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Questions? 1-800-266-9092

Distributed by:

Novara LLC
100 Pearl Street 14th Floor
Hartford, Ct 06103
USA - www.pyurx.com

Made in China



USA - www.pyurx.com
 H&M Co. Inc.
 100 Beach Street 14th Floor
 New York, NY 10038
 Distributor by:



Questions? 1-800-388-8085
 Active Ingredients: Glycolic Acid, Carbomer, Triethanolamine, Aloe, Tocopherol Acetate (Vitamin E)
 Inactive ingredients:
 • Ethyl Alcohol
 • Water
 Other information:
 • Contains 100% Natural Aloe Vera Juice

PYURX

ethanol alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80527-251
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	0.1 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	4 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	4 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	13.8 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:80527-251-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

Labeler - Novara LLC (117659846)

Establishment

Name	Address	ID/FEI	Business Operations
Novara LLC		117659846	relabel(80527-251)

Establishment

Name	Address	ID/FEI	Business Operations
Huizhou Duomei Daily Necessites Co., LTD.		554530153	manufacture(80527-251)

Revised: 9/2020

Novara LLC