

**PYURX- hand sanitizer 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.*

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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:

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.

Glycerol (1.45% v/v).

Hydrogen peroxide (0.125% v/v).

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)**

Ethyl Alcohol 75% v/v. Purpose: Antiseptic



PYURX™

# HAND 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

**33.8 FL OZ | 1000ml**

33.8 FL OZ | 1000ml

ANTI-BACTERIAL  
75% ALCOHOL

ΚΙΤΤΣ 88'88% ΟΞ ΓΕΒΙΝΣ



### Drug Facts

#### Active ingredient

Ethyl Alcohol 75% v/v .....

#### Purpose

Antiseptic

#### Use

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

#### Warnings

- 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.
- For external use only.
- Flammable, keep away from heat and flame.

- **Stop use and ask a doctor if**
- Irritation or 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 when using 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 110 °F(43°C).
- May discolor certain fabrics or surfaces.

**Inactive ingredients**

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

**Questions? 1-800-266-9092**

Made in China

**Distributed by:**

Novara LLC  
100 Pearl Street 14th Floor  
Hartford, Ct 06103  
USA - [www.pyurx.com](http://www.pyurx.com)



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Hartford, Ct 06103  
100 Pearl Street 14th Floor  
Novara LLC  
Distributed by:



Made in China

## 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 and flame.

### Do Not Use

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- 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.
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### Other information

- Store below 110F (43C)
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### Package Label - Principal Display Panel



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**33.8 FL OZ | 1000ml**



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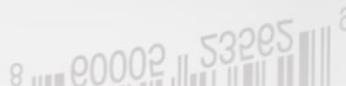
**Questions? 1-800-266-9092**

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Hartford, Ct 06103  
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## PYURX

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80527-252
<b>Route of Administration</b>	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
WATER (UNII: 059QF0KO0R)	13.8 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.1 mL in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80527-252-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/18/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2020	

**Labeler** - Novara LLC (117659846)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Novara LLC		117659846	relabel(80527-252)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Huizhou Duomei Daily Necessites Co., LTD.		554530 153	manufacture(80527-252)

Revised: 9/2020

Novara LLC