

## **PHARMA HEALTH- hand sanitizer gel gel**

**Pharma Health 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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### **Pharma Health Sanitizer Gel 5 sizes**

#### **Active Ingredient(s)**

Alcohol 75% v/v. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### **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.

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#### **Directions**

Put enough product in your palm to cover hands and rub hands together briskly until dry.

Children under 6 years of age should be supervised when using products.

#### **Other information**

Avoid freezing and excessive heat above 40C (104F)

May discolor certain fabrics or surfaces

#### **Inactive ingredients**

carbomer, triethanolamine, water

## Package Label - Principal Display Panel

3785 mL NDC: 79040-111-13

## PHARMA HEALTH

hand sanitizer gel gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79040-111
<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
CARBOMER 940 (UNII: 4Q93RCW27E)	
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79040-111-11	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
2	NDC:79040-111-12	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
3	NDC:79040-111-13	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
4	NDC:79040-111-14	40 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
5	NDC:79040-111-15	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
6	NDC:79040-111-16	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	
7	NDC:79040-111-17	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/23/2020	

**Labeler** - Pharma Health LLC (117551722)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharma Health LLC		117551722	manufacture(79040-111)

Revised: 10/2020

Pharma Health LLC