

HAND SANITIZER- isopropyl alcohol gel
Biominales Pharma, 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.

HAND SANITIZER

DRUG FACTS

Active ingredient

Isopropyl alcohol (70% v/v)

Purpose

Antiseptic

Inactive ingredients

Purified Water, Glycerin, Carbomer, Triethanolamine, Hydrogen Peroxide.

Use (s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when water and soap 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 or 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 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.

Manufactured for and

Distributed by:

Biominales Pharma, LLC
Boca Raton, Florida 33442


PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

BIOMINERALES
PHARMA

Kills more than 99.99 % of germs

HAND SANITIZER

4 oz. (118 mL)

 <p>BIOMINERALES PHARMA</p> <p>Kills more than 99.99 % of germs</p> <p>HAND SANITIZER</p> <p>4 oz. (118 mL)</p>	<p>DRUG FACTS</p> <p>Active ingredient. <i>Purpose</i> Isopropyl alcohol (70% v/v).....Antiseptic</p> <p>Inactive ingredients: Purified Water, Glycerin, Carbomer, Triethanolamine, Hydrogen Peroxide.</p>	<p>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.</p> <p>BIOMINERALES PHARMA</p> <p>Manufactured for and Distributed by: Biominales Pharma, LLC Boca Raton, Florida 33442 www.biominalespharma.com</p> <p>NDC: 77110-300-05</p>  <p>8 50018 68228 2</p>
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	<p>Warnings: <i>For external use only. Flammable. Keep away from heat or flame. Do not use</i> in children less than 2 months of age or on open skin wounds. <i>When using this product</i> keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <i>Stop use and ask a doctor</i> if irritation or rash occurs. These may be signs of a serious condition. <i>Keep out of reach of children.</i> If swallowed, get medical help or contact poison control center right away.</p>	

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:77110-300-05	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:77110-300-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
3	NDC:77110-300-03	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
4	NDC:77110-300-02	944 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
5	NDC:77110-300-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	07/15/2020	

Labeler - Biominerales Pharma, LLC (117489663)

Establishment

Name	Address	ID/FEI	Business Operations
Biominerales Pharma, LLC		117489663	MANUFACTURE(77110-300)

Revised: 7/2020

Biominerales Pharma, LLC