

ADVANCED PROTECTION HAND SANITIZING- isopropyl alcohol gel
Biominales Pharma

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.

ADVANCED PROTECTION HAND SANITIZING

DRUG FACTS

Active ingredients

Isopropyl alcohol – 70% v/v

Purpose

Antiseptic

Inactive ingredients

Deionized water, Carbomer, Propylene Glycol, 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.

Cautions and warnings

- *For external use only*

- *Flammable*

- *Keep away from heat or flame*

- *Keep out of reach of children*

- *Do not use* in children less than 2 months of age or on open skin wounds

- *When using this product* keep our of eyes, ears and mouth.

In case of contact with eyes, rinse eyes thoroughly with water

- 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.

Stop use and ask a doctor if irritation or rash occurs

Directions

Rub thoroughly into hands for at least 30 seconds, allow to dry.

Supervise children when they use this product.

Adults and children 2 years and older:

For occasional and personal domestic use.

Other information

Store Between 15-30 °C (59 - 86 °F). Avoid freezing and excessive heat above 40 °C (104 °F).

Manufactured by:

Biominaerales Pharma, LLC
150 E Palmetto Park Rd
Boca Raton, FL 33432

PRINCIPAL DISPLAY PANEL - 3,785 ml Container Label

ADVANCED PROTECTION
 HAND SANITIZING GEL

BIOMINERALES PHARMA

KILLS HARMFUL BACTERIA/GERMS

1 Gallon
 (3,785ml)

70%

v/v

ISOPROPYL
 ALCOHOL

ADVANCED PROTECTION
 HAND SANITIZING GEL



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 Boca Raton, FL 33432
 NDC: 77110-700-01



BIOMINERALES PHARMA

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 v/v ALCOHOL

ADVANCED PROTECTION HAND SANITIZING			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-700
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)	
Carbomer Homopolymer, Unspecified Type (UNII: 0A5MM307FC)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Trolamine (UNII: 9O3K93S3TK)	
Hydrogen Peroxide (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-700-04	236 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77110-700-03	473 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
3	NDC:77110-700-02	946 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	
4	NDC:77110-700-01	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	09/01/2020	

Labeler - Biominerales Pharma (117489663)

Establishment

Name	Address	ID/FEI	Business Operations
Biominerales Pharma		117489663	MANUFACTURE(77110-700)

Revised: 8/2020

Biominerales Pharma