

MEDICAL GRADE HAND SANITIZER- 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.

MEDICAL GRADE HAND SANITIZER

DRUG FACTS

Active ingredient

Ethyl alcohol (70% v/v)

Purpose

Antiseptic

Inactive ingredients

Carbomer, Glycerin, Propylene Glycol, Aminomethyl Propanol, Isopropyl Myristate, Tocopheryl Acetate, Purified Water, Fragrance.

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.

PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label

ADVANCED PROTECTION
KILLS VIRUSES AND GERMS

SCIENTIFIC
SOLUTIONS

MEDICAL GRADE GEL HAND SANITIZER

70% ALCOHOL

(236ml/8oz)

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alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77110-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMINOMETHYLPRO PANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-500-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
2	NDC:77110-500-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
3	NDC:77110-500-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	07/20/2020	

Labeler - Biominerales Pharma (117489663)

Establishment

Name	Address	ID/FEI	Business Operations
Biominerales Pharma		117489663	MANUFACTURE(77110-500)

Revised: 7/2020

Biominerales Pharma