

**HAND SANITIZER- 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.*

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**HAND SANITIZER**

**DRUG FACTS**

**Active ingredient**

Ethyl alcohol (80% v/v)

**Purpose**

Antimicrobial

**Inactive ingredients**

Water(18.025%v/v),Hydrogen Peroxide(0.125%v/v), Carbopol 940 (0.400% v/v), Glycerol (1.450% v/v).

**Use (s)**

Hand sanitizer to help reduce bacteria on the skin when water and soap are not available.

**Warnings**

**Flammable. Keep away from heat or flame.**

**For External use only. When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water for several minutes. Stop use and ask a doctor if irritation or rash occurs for more than 72 hours, consult a doctor.**

**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.

**Lot : 001 | Exp. : 05 / 2020 | NDC: 77110-200-03**

**Manufactured for and  
Distributed by:**

Biominales Pharma, LLC  
Boca Raton, Florida 33442

**PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label**

BIOMINERALES  
PHARMA

Kills more than 99.99% of germs

HAND SANITIZER - GEL

8 oz. (236 mL)

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PHARMA



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Boca Raton, Florida 33442  
www.biominalespharma.com

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77110-200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	80 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	18.025 mL in 100 mL
Hydrogen Peroxide (UNII: BBX060AN9V)	0.125 mL in 100 mL
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	0.4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77110-200-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77110-200-02	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77110-200-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
4	NDC:77110-200-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
5	NDC:77110-200-05	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

**Labeler** - Biominerales Pharma, LLC (117489663)**Establishment**

Name	Address	ID/FEI	Business Operations
Biominerales Pharma, LLC		117489663	MANUFACTURE(77110-200)

Revised: 5/2020

Biominerales Pharma, LLC