

## **TOPICARE THERAPEUTICS HAND SANITIZER- ethyl alcohol gel**

**Topicare Management, 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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### **Topicare Therapeutics Hand Sanitizer**

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

Ethyl Alcohol 73.3%

#### **Purpose**

Antiseptic, Hand Sanitizer

#### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

#### **Warnings**

**For external use only. Flammable. Keep away from heat or flame**

#### **Do not use**

On 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Wet hands thoroughly with product and allow to dry without wiping.

#### **Other information**

Store between 15-30°C (59-86°F)

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

#### **Inactive ingredients**

Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin

**Package Label - Principal Display Panel**

59mL NDC: 70112-300-02



**Topicare**  
Therapeutics



**HAND SANITIZER**  
Advanced Gel Formula

NET CONTENTS: 2 FL. OZ. (59 ML)



MADE IN U.S.A.



Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 73.3%.....	Antiseptic
<b>Uses</b>	
Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b>	
Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b>	
Do not use in eyes. In case of contact with eyes, rinse with water.	
<b>Stop use and ask a doctor if</b>	
irritation and redness develop and persist.	
<b>Keep out of reach of children</b>	
If swallowed, seek medical attention immediately.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Inactive Ingredients</b>	
Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin	
<b>Other information</b>	
Store under 105°F www.topicaretx.com 844-206-2066	



NDC: 70112-300-02

118mL NDC 70112-300-04



**Topicare**  
Therapeutics



**HAND SANITIZER**  
Advanced Gel Formula

NET CONTENTS: 4 FL. OZ. (118 ML)



MADE IN U.S.A.



Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 73.3%.....	Antiseptic
<b>Uses</b>	
Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b>	
Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b>	
Do not use in eyes. In case of contact with eyes, rinse with water.	
<b>Stop use and ask a doctor if</b>	
irritation and redness develop and persist.	
<b>Keep out of reach of children</b>	
If swallowed, seek medical attention immediately.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Inactive Ingredients</b>	
Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin	
<b>Other information</b>	
Store under 105°F www.topicaretx.com 844-206-2066	



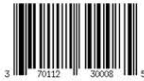
NDC: 70112-300-04

236mL NDC 70112-300-08



**HAND SANITIZER**  
**Advanced Gel Formula**

NET CONTENTS: 8 FL. OZ. (236ML)



Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 73.3%.....	Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b> Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b> Do not use in eyes. In case of contact with eyes, rinse with water.	
<b>Stop use and ask a doctor if</b> irritation and redness develop and persist.	
<b>Keep out of reach of children</b> If swallowed, seek medical attention immediately.	
<b>Directions</b> Wet hands thoroughly with product and allow to dry without wiping.	
<b>Inactive Ingredients</b> Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin	
<b>Other information</b> Store under 105°F www.topicaretx.com 844-206-2066	



NDC: 70112-300-08

473mL NDC 70112-300-16



**HAND SANITIZER**  
**Advanced Gel Formula**

NET CONTENTS: 16 FL. OZ. (473 ML)



Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 73.3%.....	Antiseptic
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b> Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b> Do not use in eyes. In case of contact with eyes, rinse with water.	
<b>Stop use and ask a doctor if</b> irritation and redness develop and persist.	
<b>Keep out of reach of children</b> If swallowed, seek medical attention immediately.	
<b>Directions</b> Wet hands thoroughly with product and allow to dry without wiping.	
<b>Inactive Ingredients</b> Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin	
<b>Other information</b> Store under 105°F www.topicaretx.com 844-206-2066	



NDC: 70112-300-16

3.79L NDC 70112-300-01



# HAND SANITIZER

## Advanced Gel Formula

NET CONTENTS: 128 FL. OZ. (1 GAL.) 3.79 L



Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 73.3%.....	Antiseptic
<b>Uses</b>	
Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b>	
Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b>	
Do not use in eyes. In case of contact with eyes, rinse with water.	
<b>Stop use and ask a doctor if</b>	
irritation and redness develop and persist.	
<b>Keep out of reach of children</b>	
If swallowed, seek medical attention immediately.	
<b>Directions</b>	
Wet hands thoroughly with product and allow to dry without wiping.	
<b>Inactive Ingredients</b>	
Klucel H hydroxypropyl cellulose, Deionized Water, Ceraphyl 31 ester, Glycerin	
<b>Other information</b>	
Store under 105°F www.topicaretx.com 844-206-2066	



NDC: 70112-300-01

### TOPICARE THERAPEUTICS HAND SANITIZER

ethyl alcohol gel

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70 112-300
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73.3 mL in 100 mL

#### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
MYRISTYL LACTATE (UNII: 1D822OC34X)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
CETYL LACTATE (UNII: A7EVH2RK4O)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70 112-300-01	3790 mL in 1 JUG; Type 0: Not a Combination Product	09/01/2020	

2	NDC:70 112-300-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
3	NDC:70 112-300-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
4	NDC:70 112-300-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
5	NDC:70 112-300-16	473 mL in 1 BOTTLE; 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	part333A	09/01/2020	

**Labeler** - Topicare Management, LLC (079902303)

## Establishment

Name	Address	ID/FEI	Business Operations
Topicare Management, LLC		079902303	manufacture(70 112-300)

Revised: 9/2020

Topicare Management, LLC