

**CANDO ULTRA HAND SANITIZER- alcohol gel**  
**Fabrication Enterprises**

*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.*

-----

**CANDO Ultra**  
**Hand Sanitizer**

***Active Ingredient***

Ethyl Alcohol 70% v/v

***Purpose***

Antiseptic

**USES**

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**WARNINGS**

**For external use only. Flammable.**

**Keep away from flame.**

**DO NOT USE**

- In children less than 2 months of age
- On open skin wounds

**WHEN USING THE PRODUCT** do not use in or near the eyes. In case of contact, 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 a Poison Control Center right away.

**DIRECTIONS**

- Put enough product in your palm to cover hands and rub hands briskly until dry.
- Children under 6 years of age should be supervised when using products.

**OTHER INFORMATION**

- Store below 104°F (40°C)
- Avoid freezing and excessive heat above 104°F (40°C)
- May discolor certain fabrics or surfaces

## INACTIVE INGREDIENTS

Aloe Vera, Carbomer Interpolymer (type B), Glycerin, Lemon oil, Triethanolamine, Water (Aqua)

## Package Label - Principal Display Panel



Drug Facts		NDC XXXXX-XXXX-X
<b>Action Ingredient</b> Ethyl Alcohol 70% v/v	<b>Purpose</b> Antiseptic	
<b>USES</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	<b>WARNINGS</b> For external use only. Flammable. Keep away from flame.	
<b>KEEP OUT OF REACH OF CHILDREN</b> If swallowed, get medical help or contact a Poison Control Center right away.	<b>WHEN USING THE PRODUCT</b> Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
<b>STOP USE AND ASK A DOCTOR</b> If irritation or rash occurs. There may be signs of a serious condition.	<b>DO NOT USE</b> • In children less than 2 months of age • On open skin wounds	

Drug Facts (continued)
<b>DIRECTIONS</b> • Put enough product in your palm • Children under 6 years of age
<b>OTHER INFORMATION</b> • Store below 104°F (40°C) • Avoid freezing and excessive above 104°F (40°C) • May discolor certain fabrics
Manufactured for: Fabrication Enterprises, Inc. 2500 Westpark Road, Suite Elmwood, NY 10823 (USA) Tel: +1-914-346-9300 Fax: +1-914-346-9300 Fabbri.com
Cando and  are trademarks.

## CANDO ULTRA HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51452-116
<b>Route of Administration</b>	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
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
LEMON OIL (UNII: I9GRO824LL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-116-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/29/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/29/2020	

**Labeler** - Fabrication Enterprises (070577218)

Revised: 9/2020

Fabrication Enterprises