

**RECENS GEL- alcohol gel**  
**Certus Medical, Inc.**

*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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**Recens Gel 6547 Drug Facts and Label**

**Drug Facts Box OTC-Active Ingredient Section**

Ethyl Alcohol 62%

**Drug Facts Box OTC-Purpose Section**

Antiseptic

**Drug Facts Box OTC-Indications & Usage Section**

for hand-washing to decrease bacteria on the skin, only when water is not available

**Drug Facts Box OTC-Warnings Section**

FLAMMABLE, keep away from fire and flames

For external use only

**Drug Facts Box OTC-When Using Section**

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

**Drug Facts Box OTC-Stop Use Section**

irritation and redness develop

**Drug Facts Box OTC-Keep Out of Reach of Children Section**

if swallowed, get medical help or contact a Poison Control Center right away

**Drug Facts Box OTC-Dosage & Administration Section**

wet hands thoroughly with product and allow to dry without wiping

**Drug Facts Box OTC-Inactive Ingredient Section**

water, triethanolamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis, dmdm hydantoin, fragrance

**Recens Gel 6547 Drug Facts and Label**

**CERTUS MEDICAL**

antiseptic  
**Recens Gel**

Instant hand sanitizer – Island Escape  
Kills 99.99% of E. coli,  
Salmonella enterica and  
Staphylococcus aureus (MRSA)  
in 15 seconds

Contains  
Vitamin E  
and Aloe  
Vera!

Reorder No.: 6547M1PM  
Net Contents: 540 ml (18.3 fl. oz.)

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Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 62%	Antiseptic
<i>Use</i> for hand-washing to decrease bacteria on the skin, only when water is not available	
<b>Warnings</b>	
Flammable, keep away from fire and flames	
For external use only	
When using this product	
<ul style="list-style-type: none"> <li>■ do not get into eyes</li> <li>■ if contact occurs, rinse eyes thoroughly with water</li> </ul>	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> <li>■ irritation and redness develop</li> </ul>	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ wet hands thoroughly with product and allow to dry without wiping</li> </ul>	
<b>Inactive Ingredients</b> water, DMDM hydantoin, disopropylamine, carbomer, propylene glycol, tocopheryl acetate, aloe barbadensis, fragrance	

6547M1PM.051820

Manufactured for Certus Medical, Inc.  
P. O. Box 16247, Atlanta, GA 30321-0247  
[www.certusmedical.com](http://www.certusmedical.com)

## Recens Gel 6547 Label

### RECENS GEL

alcohol gel

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-547
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER 934 (UNII: Z135WT9208)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-547-17	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
2	NDC:75990-547-24	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
3	NDC:75990-547-01	1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	05/18/2020	

4	NDC:75990-547-28	149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
5	NDC:75990-547-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
6	NDC:75990-547-13	800 mL in 1 BAG; Type 0: Not a Combination Product	05/18/2020	
7	NDC:75990-547-47	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
8	NDC:75990-547-05	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	
9	NDC:75990-547-55	208200 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	
10	NDC:75990-547-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/18/2020	

**Labeler** - Certus Medical, Inc. (966433653)

**Registrant** - ABC Compounding Co., Inc. (003284353)

## Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(75990-547)

Revised: 5/2020

Certus Medical, Inc.