

## **ANTI-BACTERIAL HAND GEL- ethyl alcohol gel**

**Jean Pierre 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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**Active Ingredient:** Ethyl Alcohol 62%

**Purpose** Antiseptic

**Warnings: For external use only. Flammable. Keep away from fire or flame.** Do not apply around eyes. Do not use in ears or mouth. When using this product, avoid contact with eyes. In case of contact, flush eyes with water.

Stop use or ask for a doctor if redness or irritation develops and persists for more than 72 hours.

**Keep out of reach of children.** Children must be supervised in use of this product.

**Directions:** Squeeze as needed into your palms and thoroughly spread on bottom hands. Rub into skin until dry.

**Inactive ingredients:** Water, Aloe Barbadensis Leaf, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, FD&C Blue No.1

**Uses:** Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available. Recommended for repeated use

### **Other information**

Do not store in temperature over 118 F.



## ANTI-BACTERIAL HAND GEL

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70483-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70483-001-04	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/25/2016	

**Labeler** - Jean Pierre Inc. (138328393)

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Jean Pierre Inc.