

INSTANT HAND SANITIZER GEL- ethyl alcohol gel
Bonita Pharmaceuticals 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.

Instant Hand Sanitizer Gel

Drug Facts

Active Ingredients

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- To help decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

For external use only. Flammable, keep away from fire or flame.

- **Keep out of eyes.** In case of eye contact, flush it thoroughly with water, seek medical attention immediately.
- Avoid contact with broken skin.
- **Stop use and ask a doctor if** redness or Irritation develops and persists for more than 72hrs.
- **Keep away from children.** If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction

- Place small amount of Bonita sanitizer in your palm. Thoroughly spread on both hands and rub together until dry.

Other Information

- Store below 105 °F.
- May discolor some fabrics.

Inactive Ingredients

- Water
- Propylene glycol
- Isopropyl alcohol
- PEG-12
- Carbomer 940
- Fragrance

- Triethanolamine



INSTANT HAND SANITIZER GEL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53598-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	18.6 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)

CARBOMER 940 (UNII: 4Q93RCW27E)

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53598-007-01	30 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/12/2013	

Labeler - Bonita Pharmaceuticals LLC (004219442)

Establishment

Name	Address	ID/FEI	Business Operations
Bonita Pharmaceuticals LLC		004219442	label(53598-007)

Revised: 9/2013

Bonita Pharmaceuticals LLC