SMARTCARE SHOPKINS- ethyl alcohol gel Lantern Enterprises Ltd.

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.

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

Uses

To help reduce bacteria and germs on the skin.

Directions

- Place enough product in palm to cove rhands and rub hands briskly together until dry.
- Children under 6, use only under adult supervision.
- Not recommended for infants.

Warning

Flammable. Keep away from fire or flame. For external use only.

Stop use and ask a doctor if irritation or redness develops and persists.

Inactive ingredients

aloe barbadensis gel, carbomer, fragrance, glycerin, isopropyl myristate, propylene glycol, tocopheryl acetate, triethanolamine, water





SMARTCARE SHOPKINS

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50 154-0 10

Route of Administration TOPICAL

Active Ingredient/Active Moiety

8		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90 M) (ALCOHOL - UNII: 3K9958 V90 M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

l	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	DC:50154-010-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/27/2017	

Labeler - Lantern Enterprises Ltd. (004005196)

Establishment			
Name	Address	ID/FEI	Business Operations
Shenzhen Lantern Science Co., Ltd.		421222423	manufacture(50154-010)

Revised: 10/2017 Lantern Enterprises Ltd.