ACCUBAN GEL- alcohol solution TEL Group 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.

Drug Facts

Active Ingredient

Ethyl Alcohol 70% v/v antimicrobial

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to reduce bacteria on the skin.

Warnings

Flammable. Avoid contact with open flames.

Avoid contact with eyes. If contact occurs flush immediately with plenty of water.

External use only

Stop use immediately if redness or irritation occurs and lasts.

Keep out of reach of children. If swallowed, seek medical attention right away or contact a Poison Control Center.

Directions

- Wet hands thoroughly for at lest 15 seconds
- Allow to air dry
- Supervise use by children

Other information

Store below 105F (41C)

May be damaging or discoloring to certain fabrics, wood, plastics and decorative finishes.

Inactive ingredients

Water, Isopropyl Alcohol, PEG-6 (and) AMP Acrylates/Vinyl Isodecanoate Crosspolymer, Isononyl Isononanoate, Isopropyl Myristate

Package Label - Principal Display Panel



8 fl oz (237 ml) Simple • Soothing • Safe

DRUG FACTS

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INACTIVE IN Water, Isopropyl AMP Acrylates/V Isononyl Isononai

QUESTIONS

ACCUBAN GEL

alcohol solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80620-110

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 70 L in 100 L

Inactive Ingredients

indicate ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		

Packaging

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:80620-110- 01	.237 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2020	

Labeler - TEL Group LLC (117629929)

Establishment							
Name	Address	ID/FEI	Business Operations				
TEL Group LLC		117629929	manufacture(80620-110)				

Revised: 10/2020 TEL Group LLC