

VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND WIPES- ethyl alcohol cloth
Cixi Fanhua Non Woven Products Co., 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.

Ethyl Alcohol Antiseptic Hand Wipes

Drug Facts

Active ingredient

Ethyl alcohol 75% v/v

Purpose

Antiseptic

Uses

- hand wipes to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
For external use only

Do not use

- in children less than 12 months of age
- on open skin wounds
- as a baby wipe

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

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

Directions

- open pouch by peeling back seal

- wet hands thoroughly with product and allow to dry without wiping
- reseal pouch after each use to preserve moisture
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

store below 110°F (43°C)

Inactive ingredients

alkyl dimethyl benzyl ammonium chloride, aloe extract, alpha tocopherol, decyl glucoside, glycerin, phenoxyethanol, polysorbate 20, water

Questions? +1-800-592-9541

You may also report serious side effects to this phone number.

Monday - Sunday: 24x7

FOR DAILY USE**HELPS IN DECREASING BACTERIA ON THE SKIN**

Distributed by: Sakar International

195 Carter Drive, Edison, NJ 08817

www.vivitar.com

Made in China

VIVITAR®

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Keep All Relevant Information for Future Reference.

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CAUTION : KEEP OUT OF REACH OF CHILDREN AND PETS.

Packaging

Drug Facts

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DRUG FACTS LABEL

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VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND WIPES

ethyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54826-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
ALOE (UNII: V5VD430YW9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54826-004-01	20 in 1 BAG	04/14/2021	
1		4.9 mL in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/14/2021	

Labeler - Cixi Fanhua Non Woven Products Co., Ltd (548265589)

Establishment			
Name	Address	ID/FEI	Business Operations
Cixi Fanhua Non Woven Products Co., Ltd		548265589	manufacture(54826-004)