

ALCOHOL WIPES- alcohol cloth
Enping Jiaxin Daily Necessities 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.

Alcohol Wipes

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: disinfectant

Purpose

disinfectant, Wet Wipes

Use

Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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Directions

- Wipe the body skin or other surfaces.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Aloe Barbadosis Leaf Juice, purified water USP

Package Label - Principal Display Panel



000-00

000 mL NDC: 00000-

ALCOHOL WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75111-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75111-501-01	50 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75111-501-02	60 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75111-501-03	70 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75111-501-04	80 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75111-501-05	90 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75111-501-06	100 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75111-501-07	120 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75111-501-08	150 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75111-501-09	160 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Enping Jiaxin Daily Necessities Co., Ltd. (403010421)

Establishment

Name	Address	ID/FEI	Business Operations
Enping Jiaxin Daily Necessities Co., Ltd.		403010421	manufacture(75111-501)

Revised: 7/2020

Enping Jiaxin Daily Necessities Co., Ltd.