ALCOHOL WIPES- alcohol wipes cloth Jiangyin Yunzhi Medical 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.

80538-001 Alcohol wipes

Active Ingredient(s)

Ethyl alcohol 75% antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

For external use only.

THESE WIPES DO NOT REPLACE WIPES USED FOR MEDICAL PROCEDURES.

THESE WIPES ARE MEANT FOR GENERAL CLEANSING.

Keep in a dry place away from fire.

Warnings

For external use only.

THESE WIPES DO NOT REPLACE WIPES USED FOR MEDICAL PROCEDURES.

THESE WIPES ARE MEANT FOR GENERAL CLEANSING.

Keep in a dry place away from fire.

Keep this out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Do not use in or contact the eyes.

Discontinue use if irritation and redness develop.

If the condition persists for more than 72 hours, consult a physician.

Please close the lid after dispensing to maintain purity.

Store below 95°F(35°C).

Do not use

THESE WIPES DO NOT REPLACE WIPES USED FOR MEDICAL PROCEDURES. THESE WIPES ARE MEANT FOR GENERAL CLEANSING.

Do not use in or contact the eyes.

Discontinue use if irritation and redness develop.

Keep in a dry place away from fire.

Keep this out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Do not use in or contact the eyes.

Discontinue use if irritation and redness develop.

/

Keep this out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- l.Remove lid.
- 2.Remove foil seal.
- 3. Pull wipes from centre of roll and thread through dispenser.
- 4.Ensure tab is closed after every use, to avoid evaporation.
- 5.Dispense wipes as needed.

Other information

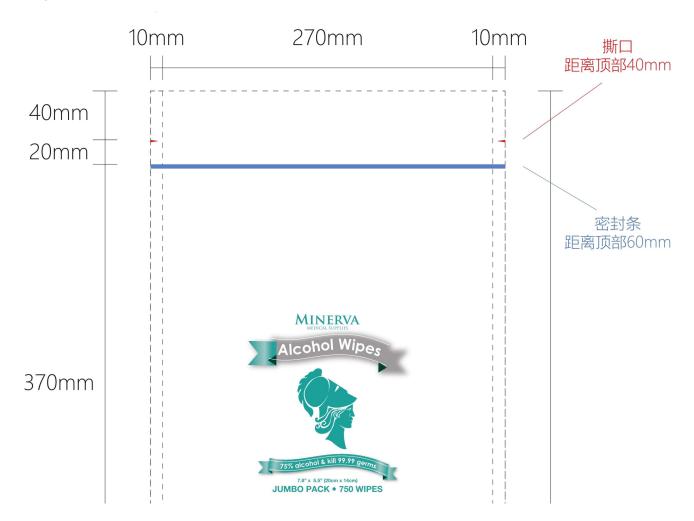
If the condition persists for more than 72 hours, consult a physician. Please close the lid after dispensing to maintain purity.

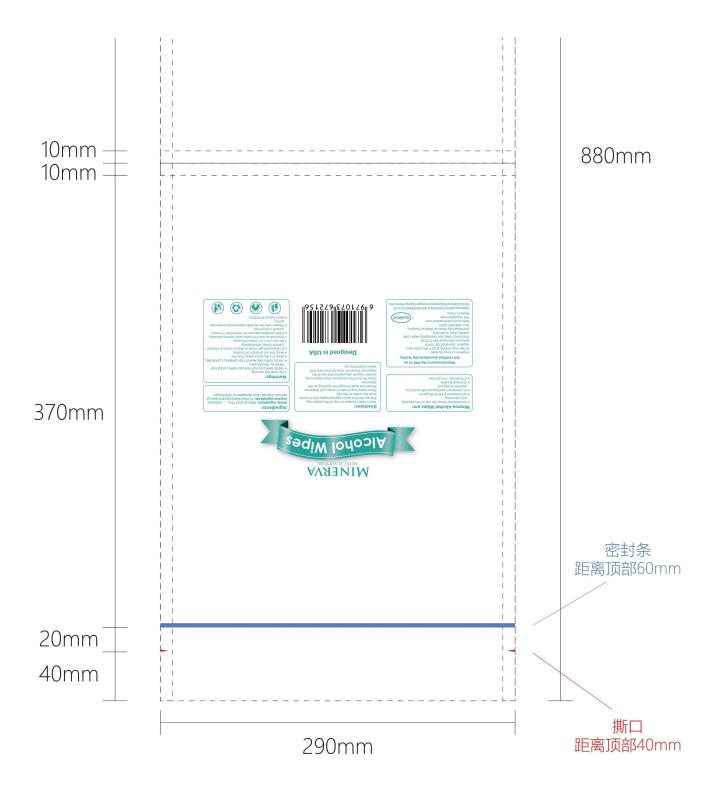
Store below 95°F(35°C).

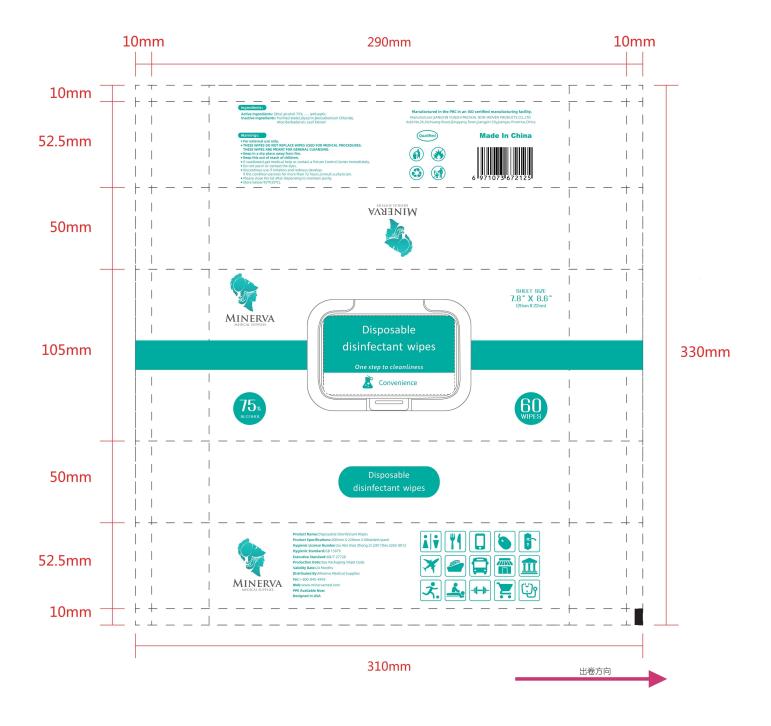
Inactive ingredients

Purified Water, Glycerin, Benzalkonium Chloride, Aloe Barbadensis Leaf Extract

Package Label - Principal Display Panel









100mm

230mm

ALCOHOL WIPES

alcohol wipes cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80538-001	
Route of Administration	TOPICAL			

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

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
BENZALKO NIUM (UNII: 7N6 JUD5X6 Y)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80538-001-01	60 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80538-001-02	320 in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80538-001-03	750 in 1 BAG; 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 - Jiangyin Yunzhi Medical Non-woven Products Co., Ltd (412717066)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jiangyin Yunzhi Medical Non-woven Products Co., Ltd		412717066	manufacture(80538-001)	

Revised: 9/2020 Jiangyin Yunzhi Medical Non-woven Products Co., Ltd