FUBU ANTISEPTIC HAND SANITIZER WIPES- benzalkonium chloride cloth BEEKMAN INTERNATIONAL INC

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.

FUBU Antiseptic Hand Sanitizer Wipes

Drug Facts

Active ingredient

Benzalkonium chloride 0.13%

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin

Warnings

For external use only

Do not use

in the eyes

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

wet hands thoroughly with product and allow to dry without wiping

Other information

- Store at room temperature.
- Keep lid tightly closed when not in use.

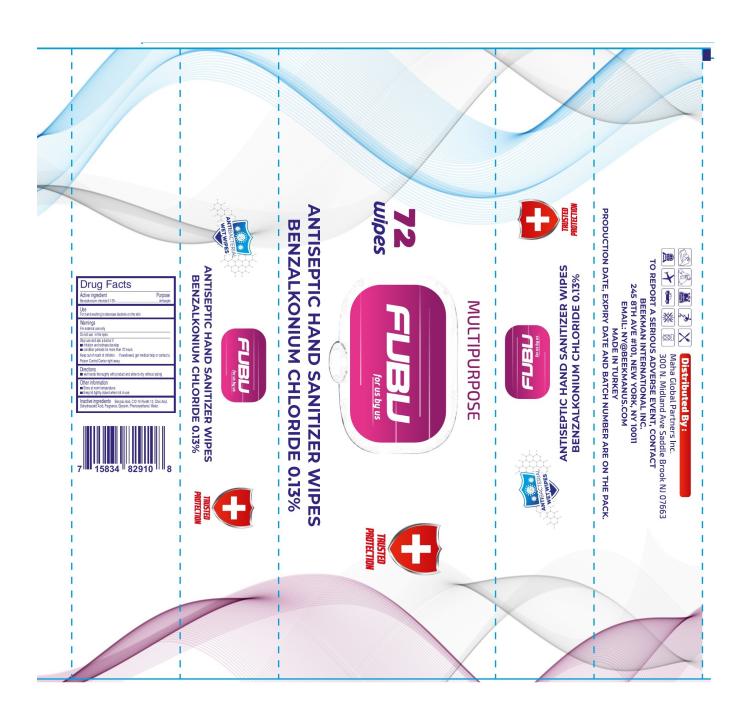
Inactive ingredients

Benzoic Acid, C12-15 Pareth 12, Citric Acid, Dehydroacetic Acid, Fragrance, Glycerin, Phenoxyethanol, Water.

Package Labeling: 15 WIPES



Package Labeling: 72 WIPES



FUBU ANTISEPTIC HAND SANITIZER WIPES

benzalkonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81321-000	
Pouts of Administration	TO PIC A I			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)			
C12-15 PARETH-12 (UNII: 131316 X18 L)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
WATER (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81321- 000-01	15 in 1 POUCH	0 1/0 1/20 21		
1		1.8 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			
2	NDC:81321- 000-02	72 in 1 POUCH	0 1/0 1/20 21		
2		3.47 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	0 1/0 1/20 21		

Labeler - BEEKMAN INTERNATIONAL INC (117679551)

Revised: 1/2021 BEEKMAN INTERNATIONAL INC