# ANTISEPTIC SANITIZING WIPES (0.13% BENZALKONIUM CHLORIDE)- benzalkonium chloride cloth

#### Jintu Handicraft Factory

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.

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#### JinTu, Wipes, Benzalkonium chloride

### **Active ingredient**

Benzalkonium Chloride 0.13% w/w. Purpose: Antiseptic

#### Purpose

Antiseptic

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

#### Do not use

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

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.

#### **Directions**

Unfold towelette, wipe hands, discard after use.

Rub thoroughly into hands for at least 30 seconds, allow to dry.

#### **Directions**

Peel back flap on front to pull out a wipe.

Unfold and wipe hands thoroughly.

Reseal and let hands dry.

No need to rinse.

#### Warnings

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

- Do not replace wipes used for medical procedures.
- These wipes are meant for general cleansing.

#### Other information

Store between 15-30 [ (59-86 [) )

## **Inactive ingredients**

purified water USP

## Package label. Principal display panel



# ANTISEPTIC SANITIZING WIPES (0.13% BENZALKONIUM CHLORIDE) benzalkonium chloride cloth Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	5.2 mg	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79846-151-21	50 in 1 POUCH; Type 0: Not a Combination Product	07/27/2020	
2	NDC:79846-151-23	60 in 1 POUCH; Type 0: Not a Combination Product	07/27/2020	
3	NDC:79846-151-25	72 in 1 POUCH; Type 0: Not a Combination Product	07/27/2020	
4	NDC:79846-151-27	80 in 1 POUCH; Type 0: Not a Combination Product	07/27/2020	
5	NDC:79846-151-31	100 in 1 POUCH; Type 0: Not a Combination Product	07/27/2020	
6	NDC:79846-151-50	100 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
7	NDC:79846-151-52	120 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
8	NDC:79846-151-56	160 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
9	NDC:79846-151-58	180 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
10	NDC:79846-151-60	200 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
11	NDC:79846-151-90	500 in 1 PAIL; Type 0: Not a Combination Product	07/27/2020	
12	NDC:79846-151-05	10 in 1 POUCH; Type 0: Not a Combination Product	11/09/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/27/2020		

# **Labeler** - Jintu Handicraft Factory (654443675)

## **Registrant -** A03 Lab of BTS (548009541)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jintu Handicraft Factory		654443675	manufacture(79846-151), label(79846-151)	

Revised: 11/2020 Jintu Handicraft Factory