

## **ANTIBACTERIAL HAND SANITIZING WIPES- benzalkonium chloride swab**

**Wuhan Bright Paper 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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### **active ingredient**

benzalkonium chloride 0.115%

antibacterial

### **Use**

hand sanitizing to decrease bacteria on the skin

### **Warnings**

For external use only.

Do not use over large areas of the body if you are allergic to any of the ingredients.

When using this product do not get in eyes. if contact occurs ,rinse throughly with water.

Stop use and ask a doctor if irritation or redness develops and continues 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**

For adults and children of 2 years and over use on hands,and face to clean and fresh,allow skin to air dry.

for children under 2 years ask a dcotor before use.

water,glycerol,propylene glycol,non-weven fabrics,coconut oil

### Drug Facts

**Active ingredient**

Benzalkonium chloride 0.115%

**purpose**

Antibacterial

**Uses:** Hand sanitizer to decrease bacteria on skin .**Warnings:**

For external use only.

**Do not use** over large areas of the body if you are allergic to any of the ingredients.**When using this product** do not get into eyes. if contact occurs, rinse thoroughly with water.**Stop use and ask a doctor** if irritation or rash develops and continues for more than 72 hours .**Keep out reach of children.** if swallowed, get medical help or contact a Poison Control Center right away .**Directions**

- For adults and children of 2 years and over use on hands and face to clean and refresh ,allow skin to air dry .
- For children under 2 years ask a doctor before use.

**Inactive ingredients**

water , glycerol ,propylene glycol,non-woven fabrics,coconut oil.

Drug Question:877-254-2281 Distributed by:90807 Farmingdale ,NY 11735

**8 Antibacterial Hand Sanitizing Wet Wipes 8 Dry Tissues**

## ANTIBACTERIAL HAND SANITIZING WIPES

benzalkonium chloride swab

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69425-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.115 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
GLYCEROL FORMAL (UNII: 3L7GR2604E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCONUT OIL (UNII: Q9L0O73W7L)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69425-001-01	1 in 1 BAG		

1		0.00828 g in 1 POUCH		
2	NDC:69425-001-02	2 in 1 BAG		
2		0.00828 g in 1 POUCH		
3	NDC:69425-001-03	3 in 1 BAG		
3		0.00828 g in 1 POUCH		
4	NDC:69425-001-04	5 in 1 BAG		
4		0.00828 g in 1 POUCH		
5	NDC:69425-001-05	8 in 1 BAG		
5		0.00828 g in 1 POUCH		
6	NDC:69425-001-06	10 in 1 BAG		
6		0.00828 g in 1 POUCH		
7	NDC:69425-001-07	15 in 1 BAG		
7		0.00828 g in 1 POUCH		
8	NDC:69425-001-08	20 in 1 BAG		
8		0.00828 g in 1 POUCH		
9	NDC:69425-001-09	30 in 1 BAG		
9		0.00828 g in 1 POUCH		
10	NDC:69425-001-10	80 in 1 BAG		
10		0.00828 g in 1 POUCH		
11	NDC:69425-001-11	100 in 1 BAG		
11		0.00828 g in 1 POUCH		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/03/2014	

**Labeler** - Wuhan Bright Paper Factory (529575810)

## Establishment

Name	Address	ID/FEI	Business Operations
Wuhan Bright Paper Factory		526890634	manufacture(69425-001)

Revised: 12/2014

Wuhan Bright Paper Factory