

**SANITIZING WIPES- benzalkonium chloride, polyaminopropyl biguanide cloth**  
**NanTong Guarder Medical Technology 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.*

-----

**Sanitizing wipes**

**Active Ingredient(s)**

Benzalkonium chloride 0.3% w/v

Polyaminopropyl biguanide 0.1% w/v.

Purpose: Antiseptic

**Purpose**

Antiseptic

**Use**

- For hand and skin cleaning
- Recommended for repeated use
- For use when soap and water are not available

**Warnings**

For external use only. Avoid contact around the eyes. If contact occurs, flush eyes with water. If the condition persists, consult a doctor. If swallowed immediately call a poison control center or a doctor for treatment advice.

**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.

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**

Wet hands thoroughly with product and allow to dry.

Discard wipes in trash receptacle after use. Do not flush.

Children under 6 years of age should be supervised when using this product.

## Other information

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

## Inactive ingredients

Water, Glycerine, Decyl Glucoside, Aloe Vera, Fructooligosaccharide, Fragrance

## Package Label - Principal Display Panel

5wipes in one box NDC:79795-004-02



## SANITIZING WIPES

benzalkonium chloride, polyaminopropyl biguanide cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79795-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POLYAMINOPROPYL BIGUANIDE</b> (UNII: DT9D8 Z79 ET) (POLYAMINOPROPYL BIGUANIDE - UNII:DT9D8 Z79 ET)	POLYAMINOPROPYL BIGUANIDE	0.1 g in 100
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.3 g in 100

## Inactive Ingredients

Ingredient Name	Strength
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79795-004-01	3 in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	11/06/2020	
2	NDC:79795-004-02	5 in 1 BAG; Type 0: Not a Combination Product	11/06/2020	
3	NDC:79795-004-03	10 in 1 BAG; Type 0: Not a Combination Product	11/06/2020	
4	NDC:79795-004-04	20 in 1 BAG; Type 0: Not a Combination Product	11/06/2020	
5	NDC:79795-004-05	50 in 1 BAG; Type 0: Not a Combination Product	11/06/2020	
6	NDC:79795-004-06	80 in 1 BAG; Type 0: Not a Combination Product	11/06/2020	
7	NDC:79795-004-07	75 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
8	NDC:79795-004-08	80 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
9	NDC:79795-004-09	100 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
10	NDC:79795-004-10	150 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
11	NDC:79795-004-11	160 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
12	NDC:79795-004-12	200 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
13	NDC:79795-004-13	600 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
14	NDC:79795-004-14	800 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
15	NDC:79795-004-15	1000 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	
16	NDC:79795-004-16	1200 in 1 BOX; Type 0: Not a Combination Product	11/06/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/06/2020	

**Labeler** - NanTong Guarder Medical Technology Co.,Ltd. (554537961)

**Registrant** - NanTong Guarder Medical Technology Co.,Ltd. (554537961)

**Establishment**

Name	Address	ID/FEI	Business Operations
NanTong Guarder Medical Technology Co.,Ltd.		554537961	manufacture(79795-004)

Revised: 11/2020

NanTong Guarder Medical Technology Co.,Ltd.