

**ANTISEPTIC SANITIZING WIPES- benzalkonium chloride cloth
HANGZHOU WIPEX NONWOVENS 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.

79294-001 ANTISEPTIC SANITIZING WIPES 0.13% BENZALKONIUM CHLORIDE

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

USE

Use for hand sanitizing to decrease bacteria on the skin recommended for repeated use.

Warning

For external use only

DO not use

In the eyes

Stop use and ask doctor if:

Irritation and redness develops

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.

Inactive ingredients

Water,Glycerin, Disodium

Cocoamphodiacetate,

Phenoxyethanol,Benzoic Acid

Polysorbate,Potassium Sorbate

Aloe barbadensia Leaf juice,

Melaleuca Alternifolia (Tea Tree) Leaf Oil,

Menthol, Sodium Citrate

Drug Facts

Active ingredient **Purpose**
Benzalkonium Chloride 0.13% Antiseptic

Uses:

- For hand washing to decrease bacteria on skin
- Recommended for repeated use.

Warnings:

For external use only

Do not use

- In the eyes

Stop use and ask doctor if:

- Irritation and redness develops
- 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 below 104°F (40°C)
- May discolor certain Fabrics

Inactive Ingredients:

Water,Glycerin, Disodium
Cocoamphodiacetate,
Phenoxyethanol,Benzoic Acid
Polysorbate,Potassium Sorbate
Aloe barbadensia Leaf juice,
Melaleuca Alternifolia (Tea Tree) Leaf Oil,
Menthol,Sodium Citrate

ANTISEPTIC SANITIZING WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79294-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
MENTHOL (UNII: L7T10EP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79294-001-01	160 in 1 CARTON	07/30/2020	
1		10 in 1 BAG		
1		60 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:79294-001-02	4 in 1 CARTON	07/30/2020	
2		1200 in 1 BAG		
2		4700 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:79294-001-03	48 in 1 CARTON	07/30/2020	
3		50 in 1 BAG		
3		237 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:79294-001-04	24 in 1 CARTON	07/30/2020	
4		80 in 1 CANISTER		
4		337 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:79294-001-05	24 in 1 CARTON	07/30/2020	
5		100 in 1 CANISTER		
5		540 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:79294-001-06	12 in 1 CARTON	07/30/2020	
6		180 in 1 CANISTER		
6		1120 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:79294-001-07	12 in 1 CARTON	07/30/2020	
7		220 in 1 CANISTER		

7		450 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:79294-001-08	4 in 1 CARTON	07/30/2020	
8		800 in 1 BAG		
8		1638 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
9	NDC:79294-001-09	4 in 1 CARTON	07/30/2020	
9		900 in 1 BAG		
9		1842 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
10	NDC:79294-001-10	4 in 1 CARTON	07/30/2020	
10		1500 in 1 BAG		
10		3071 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - HANGZHOU WIPEX NONWOVENS CO., LTD. (421323516)

Establishment

Name	Address	ID/FEI	Business Operations
HANGZHOU WIPEX NONWOVENS CO., LTD.		421323516	manufacture(79294-001)

Revised: 7/2020

HANGZHOU WIPEX NONWOVENS CO., LTD.