

CLUB WIPES USA SANITIZING WIPES- benzalkonium chloride cloth
Bubble Marketing Llc

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.

Club™ Wipes USA Sanitizing Wipes

Drug Facts

Active ingredient

Benzalkonium Chloride 0.12%

Purpose

Antiseptic

Uses

- For personal hand hygiene to help prevent the spread of bacteria.
- Use when soap and water are not available after changing diapers, assisting ill persons and before contact with a person under medical care or treatment.
- Recommended for repeat use.

Warnings

For external use only.

Do not use in the eyes.

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

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

Other information

- Store in a cool, dry place.

Inactive ingredients

Water, Aloe Barbadensis Leaf Juice, Polysorbate 20, Glycerin, Potassium Sorbate, Fragrance, Citric Acid, Disodium EDTA, Tocopheryl Acetate (Vitamin E).

Manufactured for: **BUBBLE MARKETING**

P.O. Box 19121 • Topeka, KS 66619

Tel: 785.862.0340 • Fax: 785.862.0347

www.clubwipesusa.com

Kills 99.99% of germs

- **Wet wipes cleans and sanitizes**
- **Designed to use in health facilities, health clubs, schools and wherever germs are present**
- **Board Certified Dermatologist Tested & Approved as a non-sensitizer nor irritant to skin**

DIRECTIONS FOR DISPENSING: Cut small "V" out of the bag and pull Styrofoam® core out of the center of the roll. Pull the first towel from the center of the roll approximately 6 to 8 inches. Place bag in the dispenser and at the same time feed the first towel through the opening on the dispenser.

DISPOSAL: Offer empty container for recycling. If recycling is not available, discard container in trash. Discard towel in trash after use. Do not flush.

CAUTION:May irritate eyes.

See side panel for further precautions and first aid instructions.

KEEP OUT OF REACH OF CHILDREN.

Packaging

Club Wipes USA Sanitizing Wipes

1250 Sheets • 8" x 5"



Manufactured by:
BUBBLE MARKETING

P.O. Box 19121 • Topeka, KS 66619
Tel: 785.862.0340 • Fax: 785.862.0347
www.clubwipesusa.com

Kills 99.99% of germs

- Wet wipes cleans and sanitizes
- Designed to use in health facilities, health clubs, schools and wherever germs are present
- Board Certified Dermatologist Tested & Approved as a non-sensitizer nor irritant to skin

Drug Facts

Active ingredient	Purpose
Benzalkonium Chloride 0.12%	Antiseptic

Uses

- For personal hand hygiene to help prevent the spread of bacteria.
- Use when soap and water are not available after changing diapers, assisting ill persons, and before contact with a person under medical care or treatment.
- Recommended for repeat use.

Warnings

For external use only.

Do not use in the eyes.

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

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

Other information

- Store in a cool, dry place.

Inactive ingredients

Water, Aloe Barbadosensis Leaf Juice, Polysorbate 20, Glycerin, Potassium Sorbate, Fragrance, Citric Acid, Disodium EDTA, Tocopheryl Acetate (Vitamin E).

DIRECTIONS FOR DISPENSING: Cut small "V" out of the bag and pull Styrofoam™ core out of the center of the roll. Pull the first towel from the center of the roll approximately 6 to 8 inches. Place bag in the dispenser and at the same time feed the first towel through the opening on the dispenser.

DISPOSAL: Offer empty container for recycling. If recycling is not available, discard container in trash. Discard towel in trash after use. Do not flush.

CAUTION: May irritate eyes.

See side panel for further precautions and first aid instructions.

KEEP OUT OF REACH OF CHILDREN.

CLUB WIPES USA SANITIZING WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80976-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

GLYCERIN (UNII: PDC6A3C0OX)

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80976-101-05	160 in 1 BAG	12/03/2020	
1		3.02 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:80976-101-04	900 in 1 BAG	12/03/2020	
2		3.02 mL in 1 PACKAGE; Type 0: Not a Combination Product		
3	NDC:80976-101-03	800 in 1 BAG	12/03/2020	
3		3.02 mL in 1 PACKAGE; Type 0: Not a Combination Product		
4	NDC:80976-101-02	1000 in 1 BAG	12/03/2020	
4		3.02 mL in 1 PACKAGE; Type 0: Not a Combination Product		
5	NDC:80976-101-01	1250 in 1 BAG	12/03/2020	
5		3.02 mL in 1 PACKAGE; 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	12/03/2020	

Labeler - Bubble Marketing Llc (079629047)

Revised: 4/2022

Bubble Marketing Llc