

**JANITEX ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth**  
**Pacific Health Systems Inc.**

*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.*

-----

**JANITEX Antibacterial Wet Wipes**

***Drug Facts***

***Active Ingredient***

Benzalkonium Chloride (0.2%)

***Purpose***

Antiseptic

***Uses***

- For hand sanitizing to decrease bacteria and germs on skin.
- Apply topically to the skin to help prevent cross contamination.
- Not Recommended for repeated use.
- Dries in seconds.

***Warnings***

- For external use only. Harmful if swallowed.
- Do not use as baby wipes.
- Do not use in or contact the eyes.

Avoid contact with open or exposed wounds.

***When Using***

Keep out of eyes, ears, and mouth.

In case of contact with eyes, rinse eyes thoroughly with water

***Stop Use***

Stop use if too much skin irritation and sensitivity develops or increases

**KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

***Directions***

- Open lid, gently peel back resealable label, remove and use wipes as required
- Reseal after use to avoid evaporation of alcohol it is a violation of federal law to use this product in

a manner inconsistent with its labeling.

***Other Informations***

- Store at room temperature 15-30° (59-86°F).
- Lot No. Manufacture date and expiration date can be found on package.

***Inactive Ingredients***

Aqua, Olus Oil, Glycerin, Lauryl Glucoside, Polyglyceryl-2- Dipolihydroxystearate, Glyceryl Oleate, Dicapiryl Carbonate, Perfume, Triethanolamine

**Kills 99.9% Bacteria & Germs**

**ANTIBACTERIAL**

**ANTI - FUNGAL**

**pH 5.5**

**BLEACH FREE**

Made in Turkey

**Distributed by Pacific Health Systems Inc.**

**19 Commerce Road Unit E Fairfield, NJ 07004**

**info@janitexus.com www.janitexus.com**

**Packaging**



## Antibacterial Wet Wipes

**Kills 99.9%  
Bacteria & Germs**



Drug Facts		Drug Facts (continued)
<b>Active Ingredient</b> Benzalkonium Chloride (0.2%)	<b>Purpose</b> Antiseptic	<b>When Using</b> Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
<b>Uses</b> • For hand sanitizing to decrease bacteria and germs on skin. • Apply topically to the skin to help prevent cross contamination. • Dries in seconds.		<b>Stop Use</b> Stop use if too much skin irritation and sensitivity develops or increases.
<b>Warnings</b> • For external use only. Harmful if swallowed. • Do not use as baby wipes. • Do not use in or contact the eyes. • Avoid contact with open or exposed wounds.		<b>KEEP OUT OF REACH OF CHILDREN</b> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.
<b>Uses</b> • For hand sanitizing to decrease bacteria. • Apply topically to the skin to help prevent cross contamination. • Not Recommended for repeated use. • Dries in seconds.		<b>Directions</b> • Open lid, gently peel back resealable label, remove and use wipes as required. • Reseal after use to avoid evaporation of alcohol in a manner inconsistent with its labeling.
		<b>Other Information</b> • Store at room temperature 15-30°C (59-86°F). • Lot No. Manufacture date and expiration date can be found on package.
		<b>Inactive Ingredients</b> Aqua, Olus Oil, Glycerin, Lauryl Glucoside, Polyglyceryl-2-Dipolyhydroxystearate, Glyceryl Oleate, Dioapiryl Carbonate, Perfume, Triethanolamine

**Tip de Usuario:** Usarlo General  
**Tip de Producto:** Toallas Húmedas Antibacterianas  
**Tip de Formulación:** Toallas impregnadas en Solución

**LEA LA ETIQUETA O EL PROSPECTO ANTES DE USAR EL PRODUCTO.**  
• Los niños deben usarlo bajo la supervisión de un adulto.  
• Para evitar riesgo de salud humana y ambiental, siga las instrucciones de uso.  
• Para limpiar su piel, tome unas toallas húmedas como medida de higiene personal.  
• Este es un producto diseñado para la higiene personal. Puede usar el producto con la frecuencia que desee.  
• La vida útil es de 2 años cuando se almacena a temperatura ambiente y lejos de la luz solar.  
• Sistema de Embalaje: 100 toallas.  
Benzalkonium Chloride (0.2%) (ppm) (mg/kg)

**Medidas de Precaución Adicionales:** Evite el contacto visual directo. En caso de contacto con los ojos, las áreas de contacto, al ser hoy, deben retirarse antes de lavarse. Abra los párpados y lave los ojos inmediatamente con abundante agua. Si continúa cualquier molestia, consulte a un médico.

**Advertencia e Información Importante:** No se conoce ningún efecto específico.

**Área y Forma de Uso:** Áreas públicas y personales, de alta circulación de gente.  
Dosis de Uso: Se puede usar en la cantidad requerida para la higiene personal de la piel.  
Frecuencia de Uso: Frecuencia para uso frecuente.

**Sustancias Activas (mg):** Chemical name: CAG (Number), Benzalkonium Chloride (CAS No: 10049-10-0) (0.2%)  
**Sustancias Adicionales:** Aqua, Olus Oil, Glycerin, Lauryl Glucoside, Polyglyceryl-2-Dipolyhydroxystearate, Glyceryl Oleate, Dioapiryl Carbonate, Perfume, Triethanolamine



Made in Spain  
Distributed by Pacific Health Systems Inc.  
18 Commerce Road Unit 2 Fairfax, VA 22034  
info@janitex.com www.janitex.com



## DRUG FACTS LABEL

Drug Facts		Drug Facts (continued)	
<b>Active Ingredient</b> Benzalkonium Chloride (0.2%)	<b>Purpose</b> Antiseptic	<b>When Using</b> Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Uses</b> • For hand sanitizing to decrease bacteria and germs on skin. • Apply topically to the skin to help prevent cross contamination. • Dries in seconds.		<b>Stop Use</b> Stop use if too much skin irritation and sensitivity develops or increases.	
<b>Warnings</b> • For external use only. Harmful if swallowed. • Do not use as baby wipes. • Do not use in or contact the eyes. Avoid contact with open or exposed wounds.		<b>KEEP OUT OF REACH OF CHILDREN</b> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Uses</b> • For hand sanitizing to decrease bacteria. • Apply topically to the skin to help prevent cross contamination. • Not Recommended for repeated use. • Dries in seconds.		<b>Directions</b> • Open lid, gently peel back resealable label, remove and use wipes as required. • Reseal after use to avoid evaporation of alcohol it is a violation of federal law to use this product in a manner inconsistent with its labeling.	
		<b>Other Information</b> • Store at room temperature 15-30°C (59-86°F). • Lot No. Manufacture date and expiration date can be found on package.	
		<b>Inactive Ingredients</b> Aqua, Olus Oil, Glycerin, Lauryl Glucoside, Polyglyceryl-2-Dipolyhydroxystearate, Glyceryl Oleate, Dioapiryl Carbonate, Perfume, Triethanolamine	

## JANITEX ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79519-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	<b>BENZALKONIUM CHLORIDE</b>	0.2 g in 100 mL
--	------------------------------	--------------------

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79519-010-01	72 in 1 CARTON	06/30/2020	
1		4.16 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:79519-010-02	80 in 1 CARTON	06/30/2020	
2		4.16 mL in 1 PACKAGE; Type 0: Not a Combination Product		
3	NDC:79519-010-03	100 in 1 CARTON	06/30/2020	
3		4.16 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	06/30/2020	

**Labeler** - Pacific Health Systems Inc. (080638960)

Revised: 7/2020

Pacific Health Systems Inc.