

WIPES SOLUTIONS ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth
Supplyclean Industria de Produtos de Higiene S/A

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.

WIPES SOLUTIONS ANTIBACTERIAL WET WIPES

Drug Facts

Active ingredient

Benzalkonium chloride 0.12% w/v

Purpose

Antibacterial

Uses

- hand wipes to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

- do not ingest

Stop use and ask a doctor if

- irritation and redness develop
- 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

- remove the plastic cover and pull the tip of the first wipe in the center of the roll
- insert the tip of the scarf into the center opening of the cover from the bottom up
- replace the cap, pull the first wipe and the rest will come off automatically
- wipe hands thoroughly with product and allow to dry without wiping

- dispose of the wipe in the trash
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above (104°F)

Inactive ingredients fragrance, propylene glycol

Questions? +1-844-805-8838

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM-5:00 PM

DERMATOLOGICALLY TESTED

SOFT TOUCH

PRACTICAL AND EFFECTIVE USE

READ THE LABEL CAREFULLY BEFORE USING THE PRODUCT

Do not mix with other products. Do not use for food disinfection. Do not reuse containers.

Antiseptic Wet Wipes are practical and ready to use. They have been specially developed to reduce bacteria on hands

Distributed by: Wipes Solutions Inc.

1728 NE Miami Gardens DR. Ste.209,

Miami, FL 33179

Made in Brazil

info@wipessolutions.com

Directions for use: Open the package and use the wet wipe After use, dispose of the wipe in the trash

DO NOT FLUSH

Shelf life 24 months

/supplyclean

@supplyclean

Packaging

WIPES SOLUTIONS

ANTIBACTERIAL WET WIPES

- ✦ DERMATOLOGICALLY TESTED
- ✦ SOFT TOUCH
- ✦ PRACTICAL AND EFFECTIVE USE



35 Wipes 7.1 in X 5.5 in
(20 cm X 18 cm)

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Antiseptic Wet Wipes are practical and ready to use. They have been specially developed to reduce bacteria on hands.

info@wipesolutions.com

DO NOT FLUSH



@supplyclean /supplyclean

Drug Facts (continued)

Other Information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

propylene glycol, fragrance

Questions? +1-844-805-8838

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM

Distributed by: Wipes Solutions Inc., 1728 NE Miami Gardens Dr, Ste. 209, Miami, FL - 33179

Country of origin : Brazil

READ THE LABEL
CAREFULLY BEFORE
USING THE PRODUCT

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.12% w/v.....Antibacterial

Uses

- hand wipes to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame for external use only

Drug Facts (continued)

Warnings

- Do not use
 - in children less than 2 months of age
 - on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Drug Facts (continued)

Warnings

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

Directions

- open the package and use the wet wipe
- wipe hands thoroughly with product and allow to dry
- dispose of the wipe in the trash
- supervise children under 6 years of age when using this product to avoid swallowing



DRUG FACTS LABEL

Drug Facts	Purpose
Active ingredient Benzalkonium chloride 0.12% w/w.....	Antibacterial
Uses <ul style="list-style-type: none"> • hand wipes to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available 	
Warnings For external use only Do not use <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water <ul style="list-style-type: none"> • do not ingest Stop use and ask a doctor if <ul style="list-style-type: none"> • irritation and redness develop • 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 <ul style="list-style-type: none"> • remove the plastic cover and pull the tip of the first wipe in the center of the roll • insert the tip of the scarf into the center opening of the cover from the bottom up • replace the cap, pull the first wipe and the rest will come off automatically • wipe hands thoroughly with product and allow to dry without wiping • dispose of the wipe in the trash • supervise children under 6 years of age when using this product to avoid swallowing 	
Other information <ul style="list-style-type: none"> • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above (104°F) 	
Inactive ingredients fragrance, propylene glycol	
Questions? +1-844-805-8838 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM-5:00 PM	

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80310-036
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80310-036-36	35 in 1 TUBE	08/28/2020	
1		0.00685 mL in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:80310-036-18	150 in 1 PAIL	08/28/2020	
2		0.0044 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	08/27/2020	

Labeler - Supplyclean Industria de Produtos de Higiene S/A (944745857)

Establishment

Name	Address	ID/FEI	Business Operations
Supplyclean Industria de Produtos de Higiene S/A		944745857	manufacture(80310-036)

Revised: 8/2020

Supplyclean Industria de Produtos de Higiene S/A