

ULTRACLEAN X ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth
BOSS KOZMETİK VE DİS TICARET ANONİM SİRKETİ

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.

Ultraclean X® ANTIBACTERIAL WET WIPES

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

Hand sanitizer wipes to help reduce bacteria and germs on the skin. Recommended for repeated use.

Warnings

For external use only

When using this product avoid contacting with eyes.

In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if 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

- Take wipe and rub thoroughly over all of both hands, Wet hands thoroughly with wipe and allow to dry, discard after use.
- Children under 6 years of age should be supervised when using this product.

Other information

Store at room temperature. Keep tightly closed when not use. Dispose of used wipe in trash. Do not flush.

Inactive Ingredients: Aqua (Water), Benzoic Acid, Dehydroacetic Acid, Dicaprylyl Carbonate, Glycerin, Lauryl Glucoside, Lime Oil, Phenoxyethanol, Polyglyceryl-2 Dipolyhydroxystearate

PLUS FORMULA PROTECTION

instant effect!

Free of Paraben, Dye and Phthalates

SANITIZER

ANTIBACTERIAL WET WIPES

FOR HAND SANITIZING TO DECREASE BACTERIA AND GERMS ON THE SKIN

- Sanitizing formula to help reduce cross-contamination and risk of infection.
- Leaves no stickiness or residue on hands.
- Hands feel smooth, soft and refreshed.

To Open Package:

- Flip open dispensing lid
- Locate wipe at center of roll and thread through small opening in lid
- For best results dispense wipes at an angle
- Always close lid securely between uses to retain moisture

TO DISPOSE WIPE: Place in a waste basket after use.

DO NOT FLUSH

Distributed by

Civilon LLC

Clifton, NJ, 07011

MADE IN TURKEY

OZONE FRIENDLY

Packaging

<table border="1"><thead><tr><th colspan="2">Drug Facts</th></tr></thead><tbody><tr><td>Active Ingredient</td><td>Purpose</td></tr><tr><td>Benzalkonium Chloride 0.13%</td><td>Antimicrobial</td></tr><tr><td colspan="2">Uses</td></tr><tr><td colspan="2">Hand sanitizer wipes to help reduce bacteria and germs on the skin. Recommended for repeated use.</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">For external use only</td></tr><tr><td colspan="2">When using this product avoid contacting with eyes. In case of eye contact, rinse eyes with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.</td></tr><tr><td colspan="2">Keep out of reach of children if swallowed, get medical help or contact a poison control center right away.</td></tr><tr><td colspan="2">Directions</td></tr><tr><td colspan="2">• Take wipe and rub thoroughly over all of both hands. Wet hands thoroughly with wipe and allow to dry, discard after use.</td></tr><tr><td colspan="2">• Children under 6 years of age should be supervised when using this product.</td></tr><tr><td colspan="2">Other information</td></tr><tr><td colspan="2">Store at room temperature. Keep tightly closed when not used. Dispose of used wipe in trash. Do not flush.</td></tr><tr><td colspan="2">Inactive Ingredients: Aqueous (Water), Benzoic Acid, Dehydroacetic Acid, Dicaprylyl Carbonate, Glycerin, Lauryl Glucoside, Lime Oil, Phenoxylethanol, Polyglyceryl-2 Dipolyhydroxystearate</td></tr></tbody></table>	Drug Facts		Active Ingredient	Purpose	Benzalkonium Chloride 0.13%	Antimicrobial	Uses		Hand sanitizer wipes to help reduce bacteria and germs on the skin. Recommended for repeated use.		Warnings		For external use only		When using this product avoid contacting with eyes. In case of eye contact, rinse eyes with water.		Stop use and ask a doctor if irritation or redness develops, or if 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		• Take wipe and rub thoroughly over all of both hands. Wet hands thoroughly with wipe and allow to dry, discard after use.		• Children under 6 years of age should be supervised when using this product.		Other information		Store at room temperature. Keep tightly closed when not used. Dispose of used wipe in trash. Do not flush.		Inactive Ingredients: Aqueous (Water), Benzoic Acid, Dehydroacetic Acid, Dicaprylyl Carbonate, Glycerin, Lauryl Glucoside, Lime Oil, Phenoxylethanol, Polyglyceryl-2 Dipolyhydroxystearate		  	<h2>SANITIZER ANTIBACTERIAL WET WIPES</h2> <p>FOR HAND SANITIZING TO DECREASE BACTERIA AND GERMS ON THE SKIN</p>
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<p>ANTIBACTERIAL WET WIPES</p> <p>Free of Paraben, Dye and Phthalates</p> <p>72 SANITIZING WIPES 5.6 IN X 7 IN (14.3 CM X 18 CM)</p>	<ul style="list-style-type: none">• Sanitizing formula to help reduce cross-contamination and risk of infection.• Leaves no stickiness or residue on hands.• Hands feel smooth, soft and refreshed. <p>To Open Package:</p> <ul style="list-style-type: none">• Flip open dispensing lid• Locate wipe at center of roll and thread through small opening in lid• For best results dispense wipes at an angle• Always close lid securely between uses to retain moisture  <p>8 681124 082640</p>	<p>TO DISPOSE WIPE: Place in a waste basket after use. DO NOT FLUSH</p>  <p>14.08 oz (420g) PRD DATE :01/09/2020 EXP DATE :01/09/2023</p>    																																

ULTRACLEAN X ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80445-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
LIME OIL (UNII: UZH29XGA8G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80445-101-72	72 in 1 CANISTER	08/31/2020	
1		4 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	08/31/2020	

Labeler - BOSS KOZMETİK VE DİS TİCARET ANONİM SİRKETİ (504479258)

Establishment

Name	Address	ID/FEI	Business Operations
BOSS KOZMETİK VE DİS TİCARET ANONİM SİRKETİ		504479258	manufacture(80445-101)

Revised: 9/2020

BOSS KOZMETİK VE DİS TİCARET ANONİM SİRKETİ