

**FLOVELL CARE ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth
INOSER INSAAT IC VE DIS TICARET ANONIM SIRKETI**

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Benzalkonium Chloride (0.2%, weight/weight (w/w))
- b. GLYCERYL OLEATE
- c. LAURYL GLUCOSIDE
- d. PANTHENOL
- e. PHENOXYETHANOL
- f. OCTADECANOIC ACID, (OCTADECYLIMINO)DI-2,1-ETHANEDIYL ESTER
- g. PROPYLENE GLYCOL
- h. COCAMIDOPROPYL BETAINE
- i. DICAPRYLYL CARBONATE
- j. FATTY-ACID AMIDE HYDROLASE 1
- k. GLYCERIN
- l. ALLANTOIN
- m. WATER
- n. BENZOIC ACID
- o. ANHYDROUS CITRIC ACID
- p. DEHYDROACETIC ACID
- q. ALOE VERA LEAF
- r. POLYSORBATE 20

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Benzalkonium Chloride 0.2 % (w/w) Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Standard usage Antibacterial Wet Wipes: Soak the closed and impermeable package inside hot water until it gets warm.

Microwave usage: Heat the package at 750 W for 20 seconds by tag label side openly.

Antibacterial wet wipes: whenever is necessary and needed, it can be used as 1 piece for patients to wipes.

It is used to clean who is incontinent position in need bath.

Wet wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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 use in or near eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs.

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

Directions

- Open package, remove one wet wipe to clean your hands and body. Reseal, keep closed to prevent evaporation.
- Allow to dry without wiping. Discard properly after use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store at room temperature.
- Do not flush down toilet.

Inactive ingredients

GLYCERYL OLEATE, LAURYL GLUCOSIDE, PANTHENOL, PHENOXYETHANOL, OCTADECANOIC ACID, (OCTADECYLIMINO)DI-2,1-ETHANEDIYL ESTER, PROPYLENE GLYCOL, COCAMIDOPROPYL BETAINE, DICAPRYLYL CARBONATE, FATTY-ACID AMIDE HYDROLASE 1, GLYCERIN, ALLANTOIN, WATER, BENZOIC ACID, ANHYDROUS CITRIC ACID, DEHYDROACETIC ACID
ALOE VERA LEAF, POLYSORBATE 20

Package Label - Principal Display Panel

72 pcs NDC: 86001-001-02

Drug Facts	
Active Ingredients Benzalkonium Chloride 0.25%, w/wk., Allisipic	Purpose Antibacterial
Uses Standard usage: Antibacterial Wet Wipes: Soak the closed and impermeable package inside hot water until it gets warm. Hold the package at 750 W for 20 seconds by bag label side openly. Wet Wipes: Whenever is necessary and needed, it can be used as 1 piece for patients to wipe. It is used to clean who is incontinent. Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings 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 use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs.	
Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.	
Directions Open package, remove one wet wipe to clean your hands and body. Reseal, keep closed to prevent evaporation. Do not use if dry. Discard properly after use. Supervise children under 6 years of age when using this product to avoid choking.	
Other Information Store at room temperature Do not flush down toilet	
Inactive Ingredients Allantoin, Aloe Barbadensis Leaf Juice, Benzoic Acid, Citric Acid, Cocamidopropyl Betaine, Dehydroacetic acid, Diacetyl, Glycerin, Hydroxyethyl Cellulose, Lauryl Glucoside, Olea Oil, Panthenol, Parfum, Phenoxyethanol, Polyglyceryl-2-Dipolyhydroxysebacate, Polyisobutene 20, Propylene Glycol, Water.	



ANTIBACTERIAL WET WIPES

Eliminates 99.9% of Bacteria and Germs

72 pcs

ANTIBACTERIAL maximum protection

SPECIAL FORMULA alcohol free

ULTRA SOFT gentle care



Gentle Care



Paraben Free



Ultra Soft



ANTIBACTERIAL maximum protection



SPECIAL FORMULA alcohol free



ULTRA SOFT gentle care

ANTIBACTERIAL WET WIPES

Eliminates 99.9% of Bacteria and Germs

72 pcs



ANTIBACTERIAL WET WIPES
Eliminates 99.9% of Bacteria and Germs

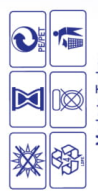
EN: Antibacterial Wet Wipes
ES: Toallitas Húmedas Antibacteriales
PT: Toalinas Antibacterianas

CAUTION: *The sticker should not get wet for keeping its adhesiveness. Please don't keep the package under direct sunlight or at high temperature.
* Keep away from the contact with eyes.

EN: Date of the manufacture and serial number on the packaging.



İNŞAAT İÇE DİŞ
TİCARET ANONİM ŞİRKETİ
ADRES : MAH/MUTBEY MAH.
2416. SK. İSTOÇ NO: 4 İÇ KAPLI
NO: 82
BAĞCILAR/ İSTANBUL



Drug Facts

Active Ingredients Purpose

Benzalkonium chloride 0.20 % w/w... Antiseptic

Uses

Standard usage Antibacterial Wet Wipes : Soak the closed and impermeable package inside hot water until it gets warm.

Microwave usage: Heat the package at 750 W for 20 seconds by tag label side openly

Antibacterial Wet Wipes : Whenever is necessary and needed, it can be used as 1 piece for patients to wipe. It is used to clean who is incontinent position in need bath.

Wet wipe to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available

Warnings

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 use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

Open package, remove one wet wipe to clean your hands and body. Reseal, keep closed to prevent evaporation.

Allow to dry without wiping. Discard properly after use.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

Store at room temperature
Do not flush down toilet

Inactive ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Benzoic Acid, Citric Acid, Cocamidopropyl Betaine, Dehydroacetic acid, Dicaprylyl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Olus Oil, Panthenol, Parfum, Phenoxethanol, Polyglyceryl-2-Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Water



ANTIBACTERIAL WET WIPES

Eliminates 99.9% of Bacteria and Germs

EN: Antibacterial Wet Wipes
ES: Toallitas Húmedas Antibacteriales
PT: Toalhetes Antibacterianas

CAUTION : *The sticker should not get wet for keeping its adhesiveness. Please don't keep the package under direct sunlight or at high temperature. * Keep away from the contact with eyes.

EN: Date of the manufacture and serial number on the packaging.

ANTIBACTERIAL WET WIPES

Eliminates 99.9% of Bacteria and Germs



+ ANTIBACTERIAL maximum protection

+ SPECIAL FORMULA alcohol free

+ ULTRA SOFT gentle care

15 pcs



İNÖSER İNŞAAT İÇ VE DİŐ
TİCARET ANONİM ŐRKETİ
ADRES : MAHMUTBEY MAH.
2416. SK. İSTOÇ NO: 4 İÇ KAPI
NO: 82
BAĞCILAR/ İSTANBUL



Made in Turkey



100 pcs NDC: 86001-001-06

Drug Facts	Active Ingredients Benzalkonium Chloride 0.25% w/wk, Allisipic	Purpose Antibacterial
Uses Standard usage: Antibacterial Wet Wipes: Soak the closed and impermeable package inside hot water until it gets warm. Then open the package at 750 W for 20 seconds by bag label side openly.	Warnings Do not use. Do not use on open skin wounds. In children less than 2 months of age use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.	Directions Open package, remove one wet wipe to clean your hands and body. Reseal, keep closed to prevent evaporation, without wiping. Discard properly after use. Supervise children under 6 years of age when using this product to avoid choking.
Other Information Store at room temperature Do not flush down toilet	Inactive Ingredients Allantoin, Aloe Barbadensis Leaf Juice, Benzoic Acid, Citric Acid, Cocamidopropyl Betaine, Dehydroacetic acid, Disodium Laureth Sulfate, Glycerin, Hydroxyethylcellulose, Methylparaben, Parfum, Phenoxyethanol, Polyglyceryl-2-Dipolyhydroxyacetate, Polyisobutene 20, Propylene Glycol, Water.	

- + ANTIBACTERIAL maximum protection
- + SPECIAL FORMULA alcohol free
- + ULTRA SOFT gentle care



ANTIBACTERIAL WET WIPES
Eliminates 99.9% of Bacteria and Germs







100 pcs



ANTIBACTERIAL WET WIPES



Eliminates 99.9% of Bacteria and Germs



ANTIBACTERIAL WET WIPES

Eliminates 99.9% of Bacteria and Germs

- + ANTIBACTERIAL maximum protection
- + SPECIAL FORMULA alcohol free
- + ULTRA SOFT gentle care

100 pcs



ANTIBACTERIAL WET WIPES
Eliminates 99.9% of Bacteria and Germs

EN: Antibacterial Wet Wipes
ES: Toallitas Húmedas Antibacteriales
PT: Toalinas Antibacterianas

CAUTION: *The sticker should not get wet for keeping its adhesiveness. Please don't keep the package under direct sunlight or at high temperature. * Keep away from the contact with eyes.
EN: Date of the manufacture and serial number on the packaging.



İNŞAAT İÇİŞİ
TİCARET ANONİM ŞİRKETİ
ADRES : MAHİMUTBEY MAH.
2416. SK. İSTOÇ NO: 4 İÇ KAPLI
NO: 82
EN: BAGLARI İSTANBUL



Made in Turkey



8 1160003 179032 114

FLOVELL CARE ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86001-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTADECANOIC ACID, (OCTADECYLIMINO)DI-2,1-ETHANEDIYL ESTER (UNII: X0S2P50TYC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
FATTY-ACID AMIDE HYDROLASE 1 (UNII: E747F394ZQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86001-001-02	72 in 1 PACKAGE	10/30/2020	
1	NDC:86001-001-01	0.008524 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:86001-001-06	100 in 1 PACKAGE	10/30/2020	
2	NDC:86001-001-05	0.008524 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:86001-001-04	15 in 1 PACKAGE	10/30/2020	
3	NDC:86001-001-03	0.008524 g in 1 PATCH; 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	10/30/2020	

Labeler - INOSER INSAAT IC VE DIS TICARET ANONIM SIRKETI (595839639)

Registrant - INOSER INSAAT IC VE DIS TICARET ANONIM SIRKETI (595839639)

Establishment

Name	Address	ID/FEI	Business Operations
LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI		502977856	manufacture(86001-001)

Revised: 12/2020

INOSER INSAAT IC VE DIS TICARET ANONIM SIRKETI