

LARA MED ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth
LARA KOZMETIK HIJYENIK URUNLERI SANAYI 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.

LARA MED Antibacterial Wet Wipes

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 (USP or Food Chemical Codex (FCC) grade) (0.15%, weight/weight (w/w)) in an aqueous solution denatured Trade Bureau regulations in 27 CFR part 20
- b. ALLANTOIN,
- c. ALOE BARBADENSIS LEAF JUICE,
- d. BENZOIC ACID,
- e. CITRIC ACID,
- f. COCAMIDOPROPYL BETAINE,
- g. DEHYDROACETIC ACID,
- h. DICAPRYLYL CARBONATE,
- i. GLYCERIN,
- j. GLYCERYL OLEATE,
- k. LAURYL GLUCOSIDE,
- l. OLUS OIL,
- m. PANTHENOL,
- n. PARFUM,
- o. PHENOXYETHANOL,
- p. POLYGLYCERYL-2-DIPOLYHYDROXYSTEARATE,
- q. POLYSORBATE 20,
- r. PROPYLENE GLYCOL,
- s. WATER

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 0.15% 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 seconds by lag 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. If irritation occurs, discontinue use.

Do not use

- in children less than 2 months of age
- on open skin wounds
- if you are allergic to chlorhexidine gluconate or any other ingredients.

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

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, PHENOXYETHANOL, POLYGLYCERYL-2-DIPOLYHYDROXYSTEARATE, POLYSORBATE 20, PROPYLENE GLYCOL, WATER

Package Label - Principal Display Panel

Drug Facts

Active Ingredients

Benzalkonium chloride 0.15 % 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
- If you are allergic to chlorhexidine gluconate or any other ingredients

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

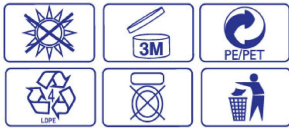


**ANTIBACTERIAL
WET WIPES**



- ✓ 0.15 % BENZALKONIUM CHLORIDE
- ✓ WITH MOISTURIZERS
- ✓ 0% ALCOHOL
(NON-STERILE WET WIPE)

**24
PCS**



Manufacturer:

Lara Kozmetik Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkgücü OSB Mah. 123. Sokak No:4/1
Çorlu / Tekirdağ/ TÜRKİYE
Tel : +90 850 711 52 72 Fax : +90 850 711 05 81
Web: <http://www.laracosmetic.com>
Mail: info@laracosmetic.com

Made in TURKEY



8 60004101413 3

Drug Facts	Purpose Benzalkonium chloride 0.15 % w/w.....Antiseptic
Active Ingredients	
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 <ul style="list-style-type: none"> ■ In children less than 2 months of age ■ On open skin wounds ■ If you are allergic to chlorhexidine gluconate or any other ingredients 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, Oils Oil, Panthenol, Parfum, Phenoxyethanol, Polyglyceryl-2-Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Water


ANTI-BACTERIAL WET WIPES



120 PCS

✓ 0.15 % BENZALKONIUM CHLORIDE ✓ WITH MOISTURIZERS ✓ 0% ALCOHOL - (NON-STERILE WET WIPE)



✓ FRESH PERFUME
✓ PARABEN FREE
✓ 0% ALCOHOL

 **ANTIBACTERIAL WET WIPES**

120 PCS



Manufacturer:
Lara Kozmetik Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçüleri OSB Mah. 123. Sokak No:4/1
Çorlu / Tekirdağ / TÜRKİYE
Tel : +90 850 711 52 72 Fax : +90 850 711 05 81
Web: <http://www.laracosmetic.com>
Mail: info@laracosmetic.com

Made in TURKEY



Drug Facts

Active Ingredients

Benzalkonium chloride 0.15 % 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
- If you are allergic to chlorhexidine gluconate or any other ingredients

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

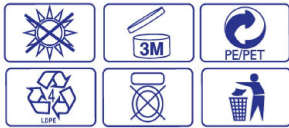


**ANTIBACTERIAL
WET WIPES**

- ✓ 0.15 % BENZALKONIUM CHLORIDE
- ✓ WITH MOISTURIZERS
- ✓ 0% ALCOHOL
(NON-STERILE WET WIPE)



**15
PCS**



Manufacturer:

Lara Kozmetik Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.

Türkgücü OSB Mah. 123. Sokak No:4/1

Çorlu / Tekirdağ/ TÜRKİYE

Tel : +90 850 711 52 72 Fax : +90 850 711 05 81

Web: <http://www.laracosmetic.com>

Mail: info@laracosmetic.com

Made in TURKEY



8 60004 01411 9

Drug Facts	Purpose Benzalkonium chloride 0.15 % w/w.....Antiseptic
Active Ingredients	
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 <ul style="list-style-type: none"> ■ In children less than 2 months of age ■ On open skin wounds ■ if you are allergic to chlorhexidine gluconate or any other ingredients 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 Barbardensis Leaf Juice, Benzoic Acid, Citric Acid, Cocamidopropyl Betaine, Dehydroacetic acid, Dicaprylyl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Olus Oil, Panthenol, Parfum, Phenoxyethanol, Polyglyceryl-2-Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Water


ANTI-BACTERIAL WET WIPES



80 PCS

✓ 0.15 % BENZALKONIUM CHLORIDE ✓ WITH MOISTURIZERS ✓ 0% ALCOHOL - (NON-STERILE WET WIPE)



- ✓ FRESH PERFUME
- ✓ PARABEN FREE
- ✓ 0% ALCOHOL

 **ANTIBACTERIAL WET WIPES**

80 PCS



Manufacturer:
Lara Kozmetik Hijyenik Urunleri San. ve Dış Tic. A.Ş.
Turgutcu OSB Mah. 123. Sokak No:4/1
Çiftlik - Teşvikiye - TÜRKİYE
Tel : +90 850 711 52 72 Fax : +90 850 711 05 01
Web: <http://www.laracosmetic.com>
Mail: info@laracosmetic.com

Made in TURKEY



Drug Facts	Active Ingredients Benzalkonium chloride 0.15 % w/w.....Antiseptic	Purpose 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 ■ If you are allergic to chlorhexidine gluconate or any other ingredients 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 Barbardensis Leaf Juice, Benzoic Acid, Citric Acid, Cocamidopropyl Betaine, Dehydroacetic acid, Dicaprylyl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Ocus Oil, Parithenol, Parfum, Phenoxyethanol, Polyglyceryl-2-Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Water



ANTIBACTERIAL WET WIPES

- ✓ 0.15 % BENZALKONIUM CHLORIDE
- ✓ WITH MOISTURIZERS
- ✓ 0% ALCOHOL (NON-STERILE WET WIPE)



EFFECTIVE AT ELIMINATING 99.9% OF MANY COMMON HARMFUL GERMS AND BACTERIA

50 PCS



ANTIBACTERIAL WET WIPES

- ✓ FRESH PERFUME
- ✓ PARABEN FREE
- ✓ 0% ALCOHOL



EFFECTIVE AT ELIMINATING 99.9% OF MANY COMMON HARMFUL GERMS AND BACTERIA

50 PCS



Manufacturer:
Lara Kozmetik Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçücu OSB Mah. 123. Sokak No:4/1
Çorlu / Tekirdağ/ TÜRKİYE
Tel : +90 850 711 52 72 Fax : +90 850 711 05 81
Web: <http://www.laracosmetic.com>
Mail: info@laracosmetic.com
Made in TURKEY



8 60004 01410 2

LARA MED ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86994-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	0.0525 g in 100 g
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	0.06 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.0375 g in 100 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.0225 g in 100 g
ALLANTOIN (UNII: 344S277G0Z)	0.06 g in 100 g
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	0.01 g in 100 g
BENZOIC ACID (UNII: 8SKN0B0MIM)	0.091 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	0.135 g in 100 g
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.588 g in 100 g
WATER (UNII: 059QF0K00R)	97.911 g in 100 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.225 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0375 g in 100 g
GLYCERYL OLEATE (UNII: 4PC054V79P)	0.01 g in 100 g
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	0.06 g in 100 g
DEXPANTHENOL (UNII: 1O6C93RI7Z)	0.15 g in 100 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	0.15 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86994-004-11	50 in 1 PACKAGE	03/30/2020	
1	NDC:86994-004-10	0.06885 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:86994-004-07	15 in 1 PACKAGE	03/30/2020	
2	NDC:86994-004-06	0.03285 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:86994-004-13	80 in 1 PACKAGE	03/30/2020	
3	NDC:86994-004-12	0.0552 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:86994-004-15	120 in 1 PACKAGE	03/30/2020	
4	NDC:86994-004-14	0.0552 g in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:86994-004-09	24 in 1 PACKAGE	03/30/2020	
5	NDC:86994-004-08	0.0139 g in 1 PATCH; Type 0: Not a Combination Product		
6	NDC:86994-004-17	100 in 1 PACKAGE	03/30/2020	
6	NDC:86994-004-16	0.0552 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	03/30/2020	

Labeler - LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI (502977856)

Registrant - LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI (502977856)

Establishment

Name	Address	ID/FEI	Business Operations
LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI		502977856	manufacture(86994-004)

Revised: 10/2020

LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI