

LARAMED ANTIBACTERIAL ALCOHOL WIPES- alcohol, isopropanol, 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.

LARAMED ANTIBACTERIAL ALCOHOL 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (65%, weight/weight (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Isopropanol 10%, (w/w)
- c. Benzalkonium Chloride 0.05%, (w/w)
- d. Glycerol
- e. Tocopherol
- f. Sterile distilled water or boiled cold 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)

Alcohol 65% w/w. Purpose: Antiseptic

Isopropanol 10% w/w. Purpose: Antiseptic

Benzalkonium chloride 0.05% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

Warnings

For external use only. Flammable liquid and vapor.

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 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 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.

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 below 110F (43 C)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surface.

Inactive ingredients

Glycerol

Tocopherol

purified water USP

Package Label - Principal Display Panel

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

120
PCS



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic
Uses	
Antibacterial alcohol wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
For external use only. Flammable liquid and vapor If irritation occurs, discontinue use.	
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 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.	
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 below 110°F (43°C) Avoid freezing and excessive heat above 104°F (40°C) May discolor certain fabrics or surface	
Inactive ingredients	
Glycerin, Tocopherol, Water.	

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

150
PCS



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic
Uses	
Antibacterial alcohol wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
For external use only. Flammable liquid and vapor If irritation occurs, discontinue use.	
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 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.	
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 below 110°F (43°C) Avoid freezing and excessive heat above 104°F (40°C) May discolor certain fabrics or surface	
Inactive ingredients	
Glycerin, Tocopherol, Water.	

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

70
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

50
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

15
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

1
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

100
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

LARAMED
CLEAN & PROTECT

ANTIBACTERIAL ALCOHOL WIPES

%75 ALCOHOL



+ effective antibacterial
+ quick drying

200
PCS



SAFETY:



DISPOSAL:



STORAGE:



Lara Kozmetik
Hijyenik Ürünleri San. ve Dış.Tic. A.Ş.
Türkçüü OSB Mah. 123. Sokak
No:4/1 Çorlu / Tekirdağ / TURKEY
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	Purpose
Ethyl Alcohol 65%w/w.....	Antiseptic
Isopropanol 10%w/w.....	Antiseptic
Benzalkonium chloride 0.05% w/w.....	Antiseptic

Uses

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

Warnings

For external use only.
Flammable liquid and vapor
If irritation occurs, discontinue use.

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 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.

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 below 110°F (43°C)
Avoid freezing and excessive heat above 104°F (40°C)
May discolor certain fabrics or surface

Inactive ingredients

Glycerin, Tocopherol, Water.

alcohol, isopropanol, benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86994-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 g in 100 g
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86994-007-32	1 in 1 PACKAGE	03/30/2020	
1	NDC:86994-007-31	3.244 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:86994-007-30	15 in 1 PACKAGE	03/30/2020	
2	NDC:86994-007-29	48.66 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:86994-007-28	50 in 1 PACKAGE	03/30/2020	
3	NDC:86994-007-27	162.2 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:86994-007-26	70 in 1 PACKAGE	03/30/2020	
4	NDC:86994-007-25	227.08 g in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:86994-007-24	100 in 1 PACKAGE	03/30/2020	
5	NDC:86994-007-23	324.4 g in 1 PATCH; Type 0: Not a Combination Product		
6	NDC:86994-007-22	120 in 1 PACKAGE	03/30/2020	
6	NDC:86994-007-21	389.28 g in 1 PATCH; Type 0: Not a Combination Product		
7	NDC:86994-007-20	150 in 1 PACKAGE	03/30/2020	
7	NDC:86994-007-19	486.6 g in 1 PATCH; Type 0: Not a Combination Product		
8	NDC:86994-007-18	200 in 1 PACKAGE	03/30/2020	
8	NDC:86994-007-17	648.8 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(86994-007)

Revised: 10/2020

LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI