

LARAMED ANTIBACTERIAL HAND SANITIZER GEL- ethyl alcohol, propan-2-ol gel
LARA KOZMETİK HIJYENİK URUNLERİ SANAYİ VE DİŞ TİCARET ANONİM ŞİRKETİ

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 Hand Sanitizer Gel

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) (70%, volume/volume (w/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Propan-2-ol (10% w/v).
- c. Glycerin
- d. Aloe vera extract
- e. Carbomer
- f. Triethanolamine
- g. 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 (ethanol)(70%, volume/volume (w/v))
Propan-2-ol (10% w/v).

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 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 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

- Place enough product in your palm to cover hands and rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 110F (43 C)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor certain fabrics or surface.
- Ethyl Alcohol % 70
- Porpan-2-ol %10
- Non sterile topical solution

Inactive ingredients

Glycerin
Aloe vera extract
Carbomer
Triethanolamine
water

Package Label - Principal Display Panel



ANTIBACTERIAL



50 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive Ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

LICENSE HOLDER and MANUFACTURER:

Lara Kozmetik Hijyenik Ürünleri San. ve Dis.Tic.A.S.
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GHS07



GHS02



8 50023 41800 5



ANTIBACTERIAL



800 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive Ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41809 8



ANTIBACTERIAL



250 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive Ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 5002341804 3



ANTIBACTERIAL



300 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41805 0



ANTIBACTERIAL



5Le

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41811 1



ANTIBACTERIAL



500 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41807 4



ANTIBACTERIAL



100 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

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

Other Information

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Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

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GHS07



GHS02



8 5002341801 2



ANTIBACTERIAL



10Le

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

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Other Information

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Avoid freezing and excessive heat above 104 °F (40 °C)

May discolor certain fabrics or surface

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41812 8



ANTIBACTERIAL



150 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41802 9



ANTIBACTERIAL



1000 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive Ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41810 4



ANTIBACTERIAL



400 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 5002341806 7



ANTIBACTERIAL



200 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 50023 41803 6



ANTIBACTERIAL



50Le

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/vAntiseptic
Propan-2-ol 10% w/vAntiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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8 50023 41813 5



ANTIBACTERIAL



750 ml e

Drug Facts

Active Ingredient

Ethyl Alcohol 70% w/v	Antiseptic
Propan-2-ol 10% w/v	Antiseptic

Purpose

Uses

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 the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

Put enough product in your palm to cover hands and rub hands together briskly until dry.

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

Alcohol 80 %

(Non-sterile Topical Solution)

Inactive Ingredients

Aloe vera extract, Carbomer, Glycerin, Triethanolamine, Water

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GHS07



GHS02



8 5002341808 1

LARAMED ANTIBACTERIAL HAND SANITIZER GEL

ethyl alcohol, propan-2-ol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:86994-008

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86994-008-01	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86994-008-02	10000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86994-008-03	50000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:86994-008-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:86994-008-13	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:86994-008-06	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:86994-008-07	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:86994-008-08	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
9	NDC:86994-008-09	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
10	NDC:86994-008-15	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
11	NDC:86994-008-16	150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
12	NDC:86994-008-17	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
13	NDC:86994-008-18	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
14	NDC:86994-008-19	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

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(86994-008)

Revised: 10/2020

LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI