

LARA MED ANTIBACTERIAL HAND SKIN CLEANER- alcohol-isopropyl alcohol aerosol, spray

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 HAND&SKIN CLEANER

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) (60.7%, volume/volume(v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Isopropyl Alcohol 8.7% (v/v)
- c. Glycerol (1.3% (v/v)
- d. BUTANE (3.25% (v/v)
- e. PROPANE (0.875% (v/v)
- f. ISOBUTANE (0.875% (v/v)
- g. FD&C Blue No.1 (0.0001% (v/v)
- h. 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 60.7% v/v. Purpose: Antiseptic

Isopropyl Alcohol 8.7% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

In order to maintain personel hygiene, it can be easily used in any environment that does not require soap without dilution.

For use when soap and water are not available. Ready to use. For use in examinations and clinics where surgical skin hygiene needed. For use before injection, and surgery and intensive care wherever hand and skin hygiene is required.

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

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, sensitization or allergin 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.

Flammable Do not use while smoking or near heat or flame

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

- use 3 ml product in your palm and hands. Rubbed well for 30 seconds. 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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Keep away sunlight.
- Pressurized container: Do not pierce or burn, even after use.

Inactive ingredients

Butane, Glycerol, Propane, Isobutane, FD&C Blue No.1, Water

Package Label - Principal Display Panel

100 mL NDC:86994-006-01

12 mm

LARA MED



KILLS 99.99 % OF GERMS
AND BACTERIA
100 ml

9 mm

Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 60.7 % v/v.....	Antiseptic
Isopropyl Alcohol 8.7 % v/v.....	Antiseptic

Uses

In order to maintain personal hygiene, it can be easily used in any environment that does not require soap without dilution. For use when soap and water are not available. Ready to use. For use in examinations and clinics where surgical skin hygiene is required. For use before injection, and surgery and intensive care wherever hand and skin hygiene is required.

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

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. 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.

Flammable Do not use while smoking or near heat or flame

Directions

Use 3 ml product in your palm and hands. Rubbed well for 30 seconds. 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 between 59-86 °F (15-30 °C) Avoid freezing and excessive heat above 104 °F (40 °C)

Keep away sunlight. Pressurized container: Do not pierce or burn, even after use.

Effective at eliminating 99.9% of many common harmful germs and bacteria with moisturizers

The product contains 65 gram liquid solution and 10 gram propellant gas. Alcohol ingredient is % 80 (v/v).

Inactive ingredients

Butane, Glycerin, Propane, Isobutane, FD&C Blue No.1, Water

Üretici / Manufacturer: Lara Kozmetik Hijyenik. Ürünler San. ve Dış. Tic. A.Ş.

Adres / Address: Türkgücü Osb mah. 123.sk. 4/1 Çorlu/ Tekirdağ/ TÜRKİYE

Web: www.laracosmetic.com - E-mail: info@laracosmetic.com

Product Code: LR-229

100 ml e MADE IN TURKEY



86994-006-02 NDC - 150 ml

LARA
MED



KILLS 99.99 % OF GERMS
AND BACTERIA
150 ml

Drug Facts

Active Ingredients

Ethyl Alcohol 60.7 % v/v.....Antiseptic
Isopropyl Alcohol 8.7 % v/v.....Antiseptic

Purpose

Uses

In order to maintain personal hygiene, it can be easily used in any environment that does not require soap without dilution. For use when soap and water are not available. Ready to use. For use in examinations and clinics where surgical skin hygiene needed. For use before injection, and surgery and intensive care wherever hand and skin hygiene is required.

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
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. 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.
Flammable Do not use while smoking or near heat or flame

Directions

Use 3 ml product in your palm and hands. Rubbed well for 30 seconds. 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 between 59-86 °F (15-30 °C)
Avoid freezing and excessive heat above 104 °F (40 °C)
Keep away sunlight.
Pressurized container: Do not pierce or burn, even after use.
Effective at eliminating 99,9% of many common harmful germs and bacteria with moisturizers
The product contains 97,5 gram liquid solution and 15 gram propellant gas.
Alcohol ingredient is % 80 (v/v).

Inactive ingredients

Butane, Glycerin, Propane, Isobutane, FD&C Blue No.1, Water

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Web: www.laracosmetic.com - E-mail: info@laracosmetic.com

150 ml e MADE IN TURKEY



86994-006-03 NDC - 300 ml



KILLS 99.99 % OF GERMS
AND BACTERIA
300 ml

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 60.7 % v/v.....	Antiseptic
Isopropyl Alcohol 8.7 % v/v.....	Antiseptic
Uses	
In order to maintain personal hygiene, it can be easily used in any environment that does not require soap without dilution. For use when soap and water are not available. Ready to use. For use in examinations and clinics where surgical skin hygiene needed. For use before injection, and surgery and intensive care wherever hand and skin hygiene is required.	
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 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. 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. Flammable Do not use while smoking or near heat or flame	
Directions	
Use 3 ml product in your palm and hands. Rubbed well for 30 seconds. 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 between 59-86 °F (15-30 °C) Avoid freezing and excessive heat above 104 °F (40 °C) Keep away sunlight. Pressurized container: Do not pierce or burn, even after use. Effective at eliminating 99,9% of many common harmful germs and bacteria with moisturizers The product contains 195 gram liquid solution and 30 gram propellant gas. Alcohol ingredient is % 80 (v/v).	
Inactive ingredients	
Butane, Glycerin, Propane, Isobutane, FD&C Blue No.1, Water	

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Web: www.laracosmetic.com - E-mail: info@laracosmetic.com

300ml e MADE IN TURKEY



LARA MED ANTIBACTERIAL HAND SKIN CLEANER

alcohol-isopropyl alcohol aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86994-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60.7 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	8.7 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.3 mL in 100 mL
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	0.0001 mL in 100 mL
WATER (UNII: 059QF0K00R)	24.2999 mL in 100 mL
BUTANE (UNII: 6LV4FOR43R)	3.25 mL in 100 mL
ISOBUTANE (UNII: BXR49TP611)	0.875 mL in 100 mL
PROPANE (UNII: T75W9911L6)	0.875 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86994-006-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86994-006-02	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86994-006-03	300 mL in 1 BOTTLE, SPRAY; 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(86994-006)

Revised: 10/2020

LARA KOZMETIK HIJYENIK URUNLERI SANAYI VE DIS TICARET ANONIM SIRKETI