

# **COVEX ANTIBACTERIAL BAR COOL PROTECTION- benzalkonium chloride soap DALAN KIMYA ENDUSTRI 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.*

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## **Covex Antibacterial Bar Soap Cool Protection**

### ***Drug Facts***

#### ***Active ingredients***

*Benzalkonium Chloride 0.13%*

#### ***Purpose***

Antibacterial

#### ***Uses***

for handwashing to decrease bacteria on the skin

#### ***Warnings***

**For external use only**

**When using this product**

#### **Do not use**

- in the eyes.

#### **Stop use and ask a doctor if**

irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Directions***

Wet hands and forearms. Apply to hands and forearms. Scrub thoroughly for 60 seconds. Rinse and repeat

#### ***Inactive ingredients:***

Sodium Tallowate, Sodium Palmate, Water, Sodium Palm Kernelate, Fragrance, Sodium Chloride, Glycerine, Zinc Oxide, C12-15 Alkyl Lactate, Titanium Dioxide, Tetrasodium EDTA, Etidronic Acid, Disodium Distyrylbiphenyl Disulfonate, Linalool, Limonene, Geraniol, Citral.

**Package Labeling:51209-022-90**



**Drug Facts**

Active ingredients	Purpose
Benzalkonium Chloride 0.13%	Antibacterial

**Uses**  
 ■ for handwashing to decrease bacteria on the skin

**Warnings**  
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To report a serious Adverse event, contact : Phone: (201) 773 8430  
\*As a result of the analysis carried out according to the ISO 17025 standards, the product was found to be effective against the microorganisms tested.  
 • Imported by: Imtrex Inc. Fair Lawn, NJ USA Phone: (201) 773 8430 www.imtrexinc.com  
 Manufactured By:  
 Dan Kimya Endustrisi A.Ş. Umit Mah. Kemalpaşa Caddesi No.325 Pınarbaşı, Izmir 35060 Turkey Made in Turkey www.dan.com.tr Phone: + 90 232 479 09 51  
 Production, Lot No and Expiry dates are on the pack.  
 00000-001

**Package Labeling:51209-022-27**



**Drug Facts**

Active ingredients	Purpose
Benzalkonium Chloride 0.13%	Antibacterial

**Uses**  
 ■ for handwashing to decrease bacteria on the skin

**Warnings**  
 For external use only  
 When using this product ■ Do not use in the eyes.  
 Stop use and ask a doctor if ■ irritation and redness develop. If condition persists for more than 72 hours consult a doctor.  
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
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**COVEX**  
 ANTIBACTERIAL BAR SOAP  
 Glycerine Formula

**Eliminates 99.9% of Germs**

**Cool Protection**  
 It's about protection and care  
 Helps to Protect Your Family

Net Wt. 9.6 oz (270 g) - 3x3.2 oz (90 g) bars

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# COVEX ANTIBACTERIAL BAR COOL PROTECTION

benzalkonium chloride soap

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51209-022
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>C12-15 ALKYL LACTATE</b> (UNII: GC844VRD7E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>ETIDRONIC ACID</b> (UNII: M2F465ROXU)	
<b>DISODIUM DISTYRYLBIPHENYL DISULFONATE</b> (UNII: 81G7704MYR)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>CITRAL</b> (UNII: T7EU009VPP)	
<b>SODIUM TALLOWATE, BEEF</b> (UNII: 07RIK6QMEW)	
<b>SODIUM PALMATE</b> (UNII: S0A6004K3Z)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM PALM KERNELATE</b> (UNII: 6H91L1NXTW)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51209-022-90	90 g in 1 BOX; Type 0: Not a Combination Product	02/24/2021	
2	NDC:51209-022-27	270 g in 1 PACKAGE; Type 0: Not a Combination Product	02/24/2021	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333E	02/24/2021	

**Labeler** - DALAN KIMYA ENDUSTRI ANONIM SIRKETI (566219285)

Revised: 3/2021

DALAN KIMYA ENDUSTRI ANONIM SIRKETI