

**DALAN THERAPY ANTIBACTERIAL HAND WASH, FRESH PROTECTION- benzalkonium chloride liquid**

**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.*

-----

**Dalan Therapy Antibacterial Hand Wash, Fresh 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 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 60 seconds. Rinse and Repeat

**Inactive ingredients:**

Water, Cocamidopropyl Betaine, Lauryl Amine Oxide, Cocamine Oxide, Cocamidopropylamine Oxide, Sodium Chloride, Glycerine, Lactic Acid, Sodium Lactate, PEG-120 Methyl Glucose Dioleate, Fragrance, Laureth-7 Citrate, Tetrasodium EDTA, Benzophenone-3, Triethylene Glycol, Propylene Glycol, Benzyl Alcohol, Methylchloroisothiazolinone, Methylisothiazolinone, Limonene, Yellow5, Blue1.

**Package Labeling:**



**Fresh Protection**

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Benzalkonium Chloride 0,13%	Antibacterial
<b>Use</b>	
For handwashing to decrease bacteria on the skin.	
<b>Warnings</b>	
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	
<b>Directions</b>	
■ Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 60 seconds. Rinse and Repeat	
<b>Inactive ingredients:</b>	
Water, Cocamidopropyl Betaine, Lauryl Amine Oxide, Cocamine Oxide, Cocoamidopropylamine Oxide, Sodium Chloride, Glycerine, Lactic Acid, Sodium Lactate, PEG-120 Methyl Glucose Diolate, Fragrance, Laureth-7 Citrate, Tetrasodium EDTA, Benzyl Alcohol-3, Triethylene Glycol, Propylene Glycol, Benzyl Alcohol, Methylchlorisothiazolinone, Methylisothiazolinone, Limonene, Yellow 5, Blue 1.	

To report a serious Adverse event, contact : Phone: (201) 773 8430  
 Imported by: Intrex Inc. Fair Lawn, NJ USA Phone: (201) 773 8430 www.intrex.us  
 Manufactured By: Dalan Kimya End. A.Ş. Ömit Mah. Kemalpaşa Cad. No.32b 35060 Pınarbaşı, İzmir, TURKEY Phone : +00 232 470 0051  
 www.dalan.com.tr **Made in Turkey**

Production, lot no and expiry dates are on the pack

Use within 12 months of opening.  
 Utiliser de préférence dans les  
 trois mois après avoir ouvert.

04543-001

UPC 7 39835 01114

**DALAN THERAPY ANTIBACTERIAL HAND WASH, FRESH PROTECTION**

benzalkonium chloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51209-016
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	

COCAMINE OXIDE (UNII: QWA2IZI6FI)
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
GLYCERIN (UNII: PDC6A3C0OX)
LACTIC ACID (UNII: 33X04XA5AT)
SODIUM LACTATE (UNII: TU7HW0W0QT)
PEG-120 METHYL GLUCOSE DIOLATE (UNII: YM0K64F20V)
EDETATE SODIUM (UNII: MP1J8420LU)
OXYBENZONE (UNII: 95OOS7VE0Y)
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
BENZYL ALCOHOL (UNII: LKG8494WBH)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51209-016-00	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/03/2020	

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

Revised: 4/2020

DALAN KIMYA ENDUSTRI ANONIM SIRKETI