

DALAN THERAPY ANTIBACTERIAL HAND WASH, COOL 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, 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 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, Methylchloroithiazolinone, Methylsothiazolinone, Linalool, Blue 1.

Package Labeling:



Cool Protection

Drug Facts	
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Benzalkonium Chloride 0.13%	Antibacterial
Use	
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To report a serious Adverse event, contact : Phone: (201) 773 8430
 Imported by: Imtrex Inc. Fair Lawn, NJ USA Phone: (201) 773 8430 www.imtrex.us
 Manufactured By: Dalan Kimya End. A.Ş. Umit Mah. Kemalpaşa Cad. No.325 35060 Pınarbaşı, İzmir, TURKEY Phone : +90 228 479 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 une fois ouvert.

04541-001

UPC 7 39835 01121

DALAN THERAPY ANTIBACTERIAL HAND WASH, COOL PROTECTION

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51209-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	

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)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51209-015-00	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

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