

COVEX ANTIBACTERIAL BAR FRESH 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.

Covex Antibacterial Bar Soap 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 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, Alpha-Isomethyl Ionone, Hexyl Cinnamal, Linalool, Limonene, Benzyl Salicylate.

Package Labeling:51209-020-90



Package Labeling:51209-020-27



Package Labeling:51209-020-34



COVEX ANTIBACTERIAL BAR FRESH PROTECTION

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51209-020
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 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM TALLOWATE, BEEF (UNII: 07RIK6QMEW)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
WATER (UNII: 059QF0K00R)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
SODIUM CHLORIDE (UNII: 451W471Q8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ETIDRONIC ACID (UNII: M2F465ROXU)	
DISODIUM DISTYRYLBIPHENYL DISULFONATE (UNII: 81G7704MYR)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X60370K2I)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

BENZYL SALICYLATE (UNII: WAO5MKN9TU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51209-020-90	90 g in 1 BOX; Type 0: Not a Combination Product	02/24/2021	
2	NDC:51209-020-27	270 g in 1 PACKAGE; Type 0: Not a Combination Product	02/24/2021	
3	NDC:51209-020-34	345 g in 1 PACKAGE; Type 0: Not a Combination Product	02/24/2021	

Marketing Information

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

Labeler - DALAN KIMYA ENDUSTRI ANONIM SIRKETI (566219285)

Revised: 2/2021

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