ANTIBACTERIAL WET WIPES- benzalkonium chloride swab
LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN

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.

Antibacterial

For external use only.Keep out of the eyes. In case of eye contact, rinse with water.If irritation develps discontinue use and consult a doctor if irritation persists more than 72 hours. If swallowed, seek medical attention or contact a Poison Control Center.

Aqua, Glycerin, Phenoxyethanol, Parfum, Polysorbate 20, Sodium PCA, Tetrasodium EDTA, Ethylhexylglycerin, Citric Acid

Benzalkonium chloride 0.13%

decreases bacteria on skin. recommended for repeated use

Keep out of the reach of children, except with adult supervision.

Take wipe and rub thoroughly over all surfaces of both hands.Rrub hands together briskly to dry·dispose of wipe. For children under 2 years ask a doctor before use.

Drug Facts

Active Ingredient (by volume) — **Purpose**
Benzalkonium Chloride 0.13% ..... Antibacterial

Uses • decreases bacteria on skin.

WARNINGS
For external use only

Do not use: Over large areas of the body if you are allergic to any of the ingredients.

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.

Keep out of reach of children.
For children under 2 years ask a doctor before use. For children use under adult supervision.

Directions
Do not expose to direct sunlight, preferably place them in a cool place. Do not use on furniture. Do not flush down toilets, dispose in trash receptacles.

Remove lid and open the seal. Pull up the corner of the center sheet, twist it and thread through the dispenser split in the lid. Pull sheet out at an angle. When finished close lid flap to retain moisture.

Inactive Ingredients: Aqua, Glycerin, Phenoxyethanol, Parfum, Polysorbate 20, Sodium PCA, Tetrasodium EDTA, Ethylhexylglycerin, Citric Acid.

ANTIBACTERIAL WET WIPES

benzalkonium chloride swab

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77892-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIMETHYLENEDIAMINETETRAACETIC ACID (UNII: 3F6OA94EER)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77892-0002-1	3 g in 1 POUCH; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN (502952094)

Establishment

Name	Address	ID/FEI	Business Operations
LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN		502952094	manufacture(77892-0002)