CREAMOL ALCOHOL WIPES- alcohol 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.

Creamol Alcohol Wipes

Alcohol (45%), Isopropyl Alcohol (30%), Benzalkonium Chloride (0,13%) (w/w)

Antiseptic

Directions

Used for hand and skin cleaning. Open the label and take one. Gently wipe your hands with an antibacterial wipe. It does not require rinsing after use.

It provides a practical cleaning without using water and soap when necessary. It helps reduce bacteria that potentially can cause disease. For use when soap and water are not available.

For external use only. Flammable, keep away from fire and flame.

Do not use on open wounds and in children less than 2 months of age

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes throughly with water.

If irritation and redness develops and persist and in case of poisoning stop use and ask a doctor. Symptoms of Poisoning are dizziness, loss of consciousness and speech disorder.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Aqua, Glycerine, Parfum, D-Panthenol, Tocopheryl Acetate

Other informations

Store between 15-30 ºC. Avoid freezing and excessive heat above 40ºC

CREAMOL ALCOHOL WIPES
alcohol swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77892-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	45 mg in 100 mg
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	30 mg in 100 mg
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PANTHENOL (UNII: WV9CM0O67Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77892-0005-1	80 mg in 1 POUCH; Type 0: Not a Combination Product	08/24/2020	
2	NDC:77892-0005-2	150 mg in 1 POUCH; Type 0: Not a Combination Product	08/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

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(77892-0005)

Revised: 8/2020

LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN