

**CLEA FANTASY ANTIBACTERIAL WET WIPES- wet wipes swab
COTTON CLUB TR HIJYENIK VE KIMYEVİ ÜRÜNLER SAN.VE DIŞ TIC.AŞ.**

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.

CLEA FANTASY ANTIBACTERIAL WET WIPES
wet wipes swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79585-250
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 g in 0.13 mg

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETIC ACID (UNII: 9G34HU7RV0)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
WATER (UNII: 059QF0K00R)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79585-250-02	150 mg in 1 POUCH; Type 0: Not a Combination Product	08/14/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/14/2020	

Labeler - COTTON CLUB TR HIJYENIK VE KIMYEVİ ÜRÜNLER SAN.VE DIŞ TIC.AŞ. (355616318)

Establishment

Name	Address	ID/FEI	Business Operations
COTTON CLUB TR HIJYENIK VE KIMYEVİ ÜRÜNLER SAN.VE DIŞ TIC.AŞ.		355616318	manufacture(79585-250)

Revised: 8/2020

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TIC.AŞ.