

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:79585-185	
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		
	BENZOIC ACID (UNII: 8SKN0B0MIM)			
	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			
	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
	EDETIC ACID (UNII: 9G34HU7RV0)			
	WATER (UNII: 059QF0K00R)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	DEHYDROACETIC ACID (UNII: 2KAG279R6R)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)			
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79585-185-80	80 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 KIMYEVI ÜRÜNLER SAN.VE DIŞ TIC.AŞ. (355616318)

Establishment

Name	Address	ID/FEI	Business Operations
COTTON CLUB TR HIJYENIK VE KIMYEVI ÜRÜNLER SAN.VE DIŞ TIC.AŞ.		355616318	manufacture(79585-185)

Revised: 8/2020

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