

CLEA FANTASY ALCOHOL WIPES- alcohol wipes swab
COTTON CLUB TR HIJYENİK VE KİMYEVİ ÜRÜNLER SAN.VE DİŞ 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.

alcohol wipes swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79585-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	45 mL in 75 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	30 mL in 75 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79585-050-50	50 mL in 1 POUCH; Type 0: Not a Combination Product	08/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/11/2020	

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(79585-050)

Revised: 7/2020

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