DISINFECTING WIPES- alcohol cloth Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd

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.

- •Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C(104°F)

Purified water USP, Didecyldimonium Chloride

Place a piece of product to rub hands and external skin, if not liquid leak from the wipe, dispose it, and use a new piece.

Alcohol

keep out of reach of children

Disinfection Sterilization No Rinseing

For external use only. Flammalbe. Keep away from heat or flame



DISINFECTING WIPES alcohol cloth					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:54345-003	
Route of Administration	TOPICAL				
Active Ingredient/Active Mo	iety				
Ingredient Name			Basis of Strength		Strength
ALCOHOL (UNII: 3K9958V90M) (AL	COHOL - UNII:3K9958V90M)		ALCOHOL		60 g in 80
Inactive Ingredients					

Ingredient Name	Strength
DIDECYLDIMO NIUM CHLO RIDE (UNII: JXN40 O9 Y9 B)	
WATER (UNII: 059QF0KO0R)	

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:54345-003-01	80 in 1 PACKET; Type 0: Not a Combination Product	08/20/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	08/20/2020			

Labeler - Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd (543259254)

Establishment					
Name	Address	ID/FEI	Business Operations		
Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd		543259254	manufacture(54345-003)		

Revised: 7/2020 Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd