## ALCOHOL ANTIBACTERIAL GEL(NONE-RINSE)- alcohol gel 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)

Purified Water USP, Triethanolamine Carbomer Glycerin

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Alcohol

keep out of reach of children

Disinfection

Sterilization

No Rinseing

- 1.For extermal use only.
- 2.Do not use in children less than 2 months of age.
- 3. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
- 4. Stop use and ask a doctor if iritation or rash occurs. This may be signs of a serious condition.
- 5.Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.



## ALCOHOL ANTIBACTERIAL GEL(NONE-RINSE)

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54345-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	60 mL in 80 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 903K93S3TK)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
GLYCERIN (UNII: PDC6A3C0OX)				

Packaging					
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:54345-002-01	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/03/2020		

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Amicus Asia Pacific(Hubei) Healthcare Products Pte Ltd		543259254	manufacture(54345-002)	

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