

SAFE HAND PLUS- alcohol gel
ACE PHARMACEUTICAL CO 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.

Drug Facts

ethanol

Glycerin

Butylene Glycol

Sodium Hyaluronate

Carbomer

Triethanolamine

Fragrance

Camellia Sinensis Leaf Extract

Aloe Barbadensis Leaf Juice

Water

hand sanitizer to help reduce bacteria that potentially can cause disease

for use when soap and water are not available

KEEP OUT OF REACH OF THE CHILDREN

Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.

Supervise children in the use of this product.

Dispense appropriate amount on your palm and thoroughly spread on both hands and rub into the skin until dry

For external use only.

Flammable, keep away from fire or flame.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation or sensitization develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

for external use only



SAFE HAND PLUS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74196-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74196-0001-1	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2020	
2	NDC:74196-0001-2	60 mL in 1 TUBE; Type 0: Not a Combination Product	04/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/02/2020	

Labeler - ACE PHARMACEUTICAL CO LTD (689058677)

Registrant - ACE PHARMACEUTICAL CO LTD (689058677)

Establishment			
Name	Address	ID/FEI	Business Operations
ACE PHARMACEUTICAL CO LTD		689058677	manufacture(74196-0001)

Revised: 4/2020

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