PACOMERI ADVANCED HAND SANITIZER- alcohol gel Newfeel

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.

ACTIVE INGREDIENT

Active ingredients: Ethyl alcohol 75% v/v

INACTIVE INGREDIENT

Inactive ingredients:

PURIFIED WATER, CARBOMER, BUTYLENE GLYCOL, GLYCERIN, SODIUM HYALURONATE, TRIETHANOLAMINE, FRAGRANCE

PURPOSE

Purpose: Antiseptic

WARNINGS

Warnings:

For external use only: hands

Flammable, keep away from fire or flame.

When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water.

■ avoid contact with broken skin. ■ do not inhale or ingest

Stop use and ask a doctor if ■irritation and redness develop ■ condition persists for more than 72 hours Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Uses:

- for handwashing to decrease the bacteria on the skin
- recommended for repeated use

Directions

Directions:

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

Other information

Other information

- do not store above 105
- may discolor some fabrics
- harmful to wood finishes and plastics

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





PACOMERI ADVANCED HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73713-060	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	375 mL in 500 mL		

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		

Glycerin (UNII: PDC6A3C0OX)	
HYALURONATE SO DIUM (UNII: YSE9 PPT4TH)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73713-060- 01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 4/0 1/20 20	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Newfeel (690062383)

Registrant - Newfeel (690062383)

Establishment				
Name	Address	ID/FEI	Business Operations	
Newfeel		690062383	manufacture(73713-060)	

Revised: 5/2020 Newfeel