PRIMEGEL ANTISEPTIC HAND SANITIZER GEL 80 ETHYL ALCOHOL- alcohol gel
FIGUEIRA E FELICIANO INDUSTRIA DE COSMETICOS LTDA

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.

PrimeGel Antiseptic Hand Sanitizer Gel 80% Ethyl Alcohol

Drug Facts

Active ingredient

Ethyl Alcohol 80%

Purpose

Antiseptic

Use

for hand washing to decrease bacteria on the skin.

Warnings

For external use only.
Flammable, keep away from fire or flame.

Do not use

in the eyes.

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.

Directions

Wet hands thoroughly with product and allow to dry without wiping.

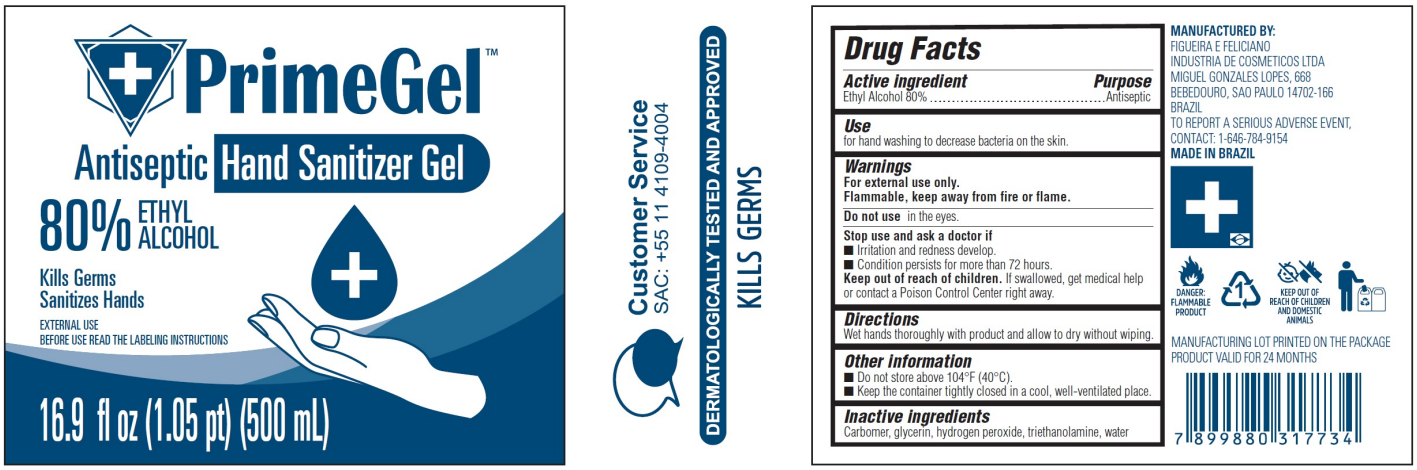
Other information

- Do not store above 104°F (40°C).
- Keep the container tightly closed in a cool, well-ventilated place.

Inactive ingredients

Carbomer, glycerin, hydrogen peroxide, triethanolamine, water

Package Labeling:



PRIMEGEL ANTISEPTIC HAND SANITIZER GEL 80 ETHYL ALCOHOL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81717-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:81717-001-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2021	

Labeler - FIGUEIRA E FELICIANO INDUSTRIA DE COSMETICOS LTDA (903595328)

Revised: 5/2021 FIGUEIRA E FELICIANO INDUSTRIA DE COSMETICOS LTDA