

PREPIEL K365 CLEAN GEL- alcohol gel
JMB COSLINE 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.

JMB COSLINE CO.,LTD - Prepiel K365 CLEAN GEL
90028-070-01
500 mL

Active ingredient

Alcohol 70% w/wAntiseptic

Use

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.
- Avoid direct inhalation of vapors during application.

(Headaches and irritation to mucous membranes may occur when directly inhaled.)

- This product is intended only for hand sanitizing.
- To prevent contents from drying out and contaminants from entering, close lid completely after use.
- Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.
- Do not use over bandages, castings, etc. as irritation may occur.

Other information

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

Inactive ingredients

Water, Butylene Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Triethanolamine, Fragrance



PREPIEL K365 CLEAN GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90028-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90028-070-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/09/2021	

Labeler - JMB COSLINE CO.,LTD (694837486)**Establishment**

Name	Address	ID/FEI	Business Operations
JMB COSLINE CO.,LTD		694837486	manufacture(90028-070)

Revised: 2/2021

JMB COSLINE CO.,LTD