

BIOMEDIK PREMIUM HAND SANITIZER GEL- alcohol gel SISKINKOREA 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.

BIOMEDIK Premium Hand Sanitizer Gel [74514-5570-1] 500 mL, Bottle+Pump



BIOMEDIK PREMIUM HAND SANITIZER GEL

ANTISEPTIC

70% Alcohol with panthenol and hyaluronic acid extracts to keep your hands fresh and clean.

Drug Facts

Active Ingredients	Purpose
Alcohol	Antiseptic

Uses
Use sanitizer to help reduce bacteria that contribute to common diseases.
Use on external areas of hands and feet only.

Warnings
For external use only. Flammable. Keep away from heat or flames.
Directions
Use as directed. Wash hands thoroughly with water.
When using this product may irritate or cause dryness, redness, or itching.
Stop use and ask a doctor if irritation or rash occurs. There may be signs of allergic reaction.
Keep out of reach of children if swallowed, get medical help; or contact a poison control center.

Directions
• Rub enough product on hands to cover all surfaces. Rub hands together for 20 seconds, adjust order if easier to remember when using the product to avoid missing.
• Avoid direct inhalation of vapors during application. Inhalation and irritation to mucous membranes may occur when directly inhaled.
• The product is intended only for hand sanitizing.
• To prevent contents from drying out and contaminants from entering, close the cap immediately after use.
• Keep product in its original container. Do not use the product in a sealed container after the original cap has been removed or after the integrity of the product is damaged.
• Do not use over blemishes, sores, cuts, or abrasions.

Other information
• Store between 15-30 °C (59-86 °F).
• Keep away from children and pets.
Active Ingredients Water, Glycerin, Glycerol, Antiseptic Propylol, Sodium Hyaluronate, Panthenol.

MANUFACTURED BY SISKINKOREA CO., LTD.
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(LOT EXP. DATE) MARKED SEPARATELY

MADE IN KOREA

BIOMEDIK PREMIUM HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74514-5570
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
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74514-5570-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

Labeler - SISKINKOREA CO.,LTD. (695625974)**Establishment**

Name	Address	ID/FEI	Business Operations
SISKINKOREA CO.,LTD.		695625974	manufacture(74514-5570)

Revised: 5/2020

SISKINKOREA CO.,LTD.