DR. JAMES GEL (ETHANOL)- alcohol gel WOORILIFE&HEALTH

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.

Woorilife&Health - Dr.James Gel

alcohol

glycerin, triethanolamine, carbomer, lemon oil, aloe vera gel, hinoki oil, green tea extract, edta, water antiseptic

Take moderate amount on hands and rub well to dry

• Adults and children 2 years of age and older

Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or docter.

• Children under 6 years

To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.

• Children under 2 years

Consult a dentist or doctor

- 1) Be careful not to swallow it, and rinse your mouth thoroughly after use.
- 2) If any abnormalities such as gum or mouth damage are caused by using this toothpaste, stop using the product and consult a doctor or dentist.
- 3) For children under 6 years of age, use a small amount of pea toothpaste per serving and use it under the supervision of a guardian to avoid sucking or swallowing.
- 4) If a child under 6 years of age swallows a large amount, consult a doctor or dentist immediately.
- 5) Keep out of reach of children under 6 years old.

for external use only



DR. JAMES GEL (ETHANOL)

alcohol gel

Dro	duct	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73065-0005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
TROLAMINE (UNII: 9O3K93S3TK)		
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
GLYCERIN (UNII: PDC6A3C0OX)		
EDETIC ACID (UNII: 9G34HU7RV0)		
LEMON OIL (UNII: 19 GRO 8 2 4 LL)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73065-0005-1	100 mL in 1 TUBE; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2020	

Labeler - woorilife&health (694860803)

Registrant - WOORILIFE&HEALTH (694860803)

Establishment			
Name	Address	ID/FEI	Business Operations
WOORILIFE&HEALTH		694860803	manufacture(73065-0005)

Revised: 6/2020 WOORILIFE&HEALTH