HERBION NATURALS ADVANCED HAND SANITIZER- alcohol gel Herbion Pakistan (Pvt.) 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.

Active ingredient

Ethyl alcohol 70 %

Purpose

Antimicrobial

Uses:

- Hand sanitizer to help reduce bacteria on the skin that cause disease
- Recommended for repeated use

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Place enough product in your palm to thoroughly cover your hands Run hands together briskly until dry Children under 6 years of age should be supervised when using this product.

Other Information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

Carbomer, Fragrance, Glycerin, Isopropyl Myristate, Trolamine, Water (Aqua)

USA 60 ml

29.5 mm

Drug Facts Active ingredient Purpose Ethyl alcohol 70% v/v...... Antimicrobial Uses · Hand sanitizer to help reduce bacteria on the skin that cause disease • Recommended for repeated use Warnings Flammable. Keep away from fire or flame. For external use only When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. **Directions** Place enough product in your palm to thoroughly cover your hands
 Rub hands together briskly until dry
 Children under 6 years of age should be supervised when using this product. Other Information
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Carbomer, Fragrance, Glycerin,
Isopropyl Myristate, Trolamine, 6 Water (Aqua) 2 Manufactured for: 0 Herbion USA, Inc. Hicksville, NY 11801 1-888 (OK-HERBION)-654-3724 info@herbion.us, www.herbion.us

29.5 mm



HERBION NATURALS ADVANCED HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:44237-042-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/21/2020		

Labeler - Herbion Pakistan (Pvt.) Ltd (645482936)

Registrant - Herbion Pakistan (Pvt.) Ltd (645482936)

Establishment				
Name	Address	ID/FEI	Business Operations	
Herbion Pakistan (Pvt.) Ltd		645482936	manufacture(44237-042)	

Revised: 3/2020 Herbion Pakistan (Pvt.) Ltd