

VFENDER HAND SANITIZER GEL- alcohol gel

Nara Parts Industries, LLC

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(s)

Alcohol 72% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria on the skin.
Recommended for repeated use.

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.

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Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.
- Not recommended for infants.

Other information

- Do not store above 105°F (40°C).
- May discolor certain fabrics.
- Harmful to wood finishes and plastics.

Inactive ingredients

Carbomer, Glycerin, Lemon Oil, L-Menthol, Tocopheryl Acetate, Triethanolamine, Water.

Package Label - Principal Display Panel



VFENDER HAND SANITIZER GEL			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80387-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)		ALCOHOL	72 mL in 100 mL
Inactive Ingredients			

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80387-100-10	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/24/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

Labeler - Nara Parts Industries, LLC (969483622)

Registrant - Nara Parts Industries, LLC (969483622)

Establishment

Name	Address	ID/FEI	Business Operations
WORLDCHEM CO., LTD.		631058864	manufacture(80387-100)

Establishment

Name	Address	ID/FEI	Business Operations
Nara Parts Industries, LLC		969483622	relabel(80387-100)