

ISOPROPYL ALCOHOL- vp biomed liquid PENSEUR KREATIVA GROUP

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.

VP BIOMED ISOPROPYL ALCOHOL

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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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.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3785 ml NDC: 81227-004-00

NEW

GO

GERMSOUT

ISOPROPYL ALCOHOL

70%

NDC: 79878-003-00
CONT. NET 1 GALLON (3785 ML)

EXPIRATION DATE : 08/2023 • LOT. 10000 08082020

ACTIVE INGREDIENTE	PURPOSE
ISOPROPYL ALCOHOL 70%	ANTIMICROBIAL

USES: FIRST AID TO HELP PREVENT THE RISK OF INFECTION IN MINOR CUTS, SCRAPES, AND BURNS.

Warnings
For external use only.
 • IF TAKEN INTERNALLY, SERIOUS GASTRIC DISTURBANCES WILL RESULT
Flammable, keep away from fire or flame.
 • use only in a well-ventilated area; fumes may be toxic

Ask a doctor before use if you have: deep or puncture wounds, animal bites, or serious burns.

When using this product:
 • do not get into eyes
 • do not apply over large areas of the body
 • do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse.

Keep out of reach of children. In case of ingestion, get medical help or contact a poison control center right away (1-800-222-1222), or (911)

Directions:
 • clean affected area
 • apply small amount of this product on the area 1-3 times daily
 • if bandaged, let dry first
 • may be covered with a sterile bandage

Other information:
 • store at room temperature
 • do not contain, nor is intended as a substitute for grain or ethyl alcohol

Inactive ingredient: purified water, glycerin, hydrogen peroxide USP

QUESTIONS? 1 (718) 831 7156 YOU MAY ALSO REPORT SERIOUS SIDE EFFECTS TO THIS PHONE NUMBER MON-FRI 9 AM - 5 PM

DISTRIBUTED IN THE UNITED STATES BY: PENSEUR PRODUCTS GROUP LLC ADDRESS: 1750 N BAYSHORE DR, APT 3508 MIAMI FL 33132 POSTAL CODE: 33132-3213.

DISTRIBUTED IN P.R. BY: NG TRADING PO BOX 16206 SAN JUAN PR 00908 NICKY GONZALEZ NG TRADING PHONE NUMBER (787) 505-9000



0 701575 381906




MADE IN DOMINICAN REPUBLIC.

VP BIOMED - ISOPROPYL ALCOHOL

3785 ML

NDC 81227-008-00



ISOPROPYL ALCOHOL

ALCOHOL ISOPROPILICO

**ANTISEPTICO
ANTISEPTIC**
CONT. NET
1 GALON 128 OZ

70%



Drug Facts	
ACTIVE INGREDIENT ISOPROPYL ALCOHOL 70 %.....	PURPOSE ANTIMICROBIAL
USES: HAND SANITIZER TO HELP REDUCE BACTERIA THE SKIN	
WARNING: 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 THROUGLY WITH WATER.	
STOP USE AND ASK A DOCTOR IF. IRRITATION OR RASH APPEARS AND LASTS.	
DIRECTIONS PLACE PRODUCT ON HANDS * RUB UNTIL DRY	
INACTIVE INGREDIENTS WATER (AQUA), ISOPROPYL ALCOHOL, GLYSERIN	
QUESTIONS? 1 (718) 831-7156 YOU MAY ALSO REPORT SERIOUS SIDE AFFECTS TO THIS PHONE NUMBER MON – FRI 9:AM – 5 AM.	
DISTRIBUIDO POR: PAOLA ENTERPRISES, PARA VP BIOMED LLC, GUAYNABO P.R. TEL. 787-988-2328	

ISOPROPYL ALCOHOL

vp biomed liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81227-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81227-008-00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:81227-008-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:81227-008-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:81227-008-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	

Drug Facts

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - PENSEUR KREATIVA GROUP (817469188)

Registrant - PENSEUR KREATIVA GROUP (817469188)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 2/2022

PENSEUR KREATIVA GROUP