DERMONANO- alcohol gel PGH LABORATORIOS DO BRASIL LTDA.

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

Antiseptic

Use

Hand rub to help reduce bacteria that potentially can cause disease when water is 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.

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

Aqua, Carbomer, Isopropyl Alcohol, Aminomethyl Propanol, Panthenol, Triisopropanolamine

Questions or Comments

PGH Laboratorios do Brasil Ltda.

SAC (931) 444-6323

sac@dermonano.com.br

Principal Display Panel

NDC: 75751-070-04

Gel 70% (alcohol) - Read Instructions before use contains Hydrated Ethyl Alcohol 70 INPM

Gel 70% (alcohol)

Sanitation Effective against bacteria and germs

Requires no water

Danger: Flammable

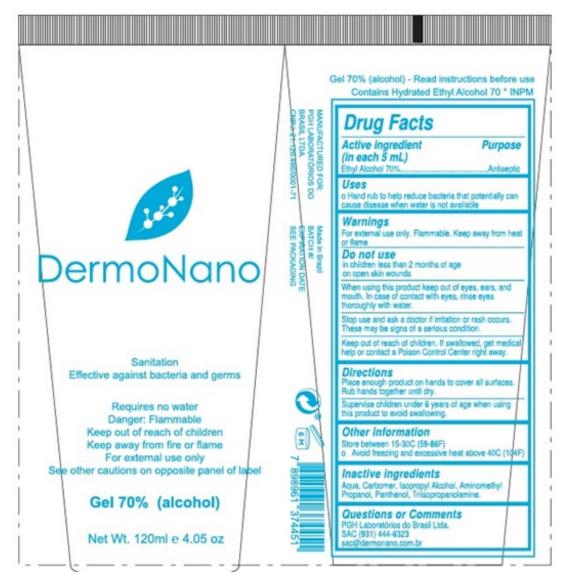
Keep out of reach of children

Keep away from fire or flame

For external use only

See other cautions on opposite panel of label

Net Wt. 120g e 4.2 oz



NDC: 75751-070-16

Gel 70% (alcohol) - Read Instructions before use contains Hydrated Ethyl Alcohol 70 INPM

Gel 70% (alcohol)

Sanitation Effective against bacteria and germs

Requires no water

Danger: Flammable

Keep out of reach of children

Keep away from fire or flame

For external use only

See other cautions on opposite panel of label

Gel 70% (alcohol)

Net Wt. 480g e 16.9 oz



NDC: 75751-070-26

Gel 70% (alcohol) - Read Instructions before use contains Hydrated Ethyl Alcohol 70 INPM

Gel 70% (alcohol)

Sanitation Effective against bacteria and germs

Requires no water

Danger: Flammable

Keep out of reach of children

Keep away from fire or flame

For external use only

See other cautions on opposite panel of label

Gel 70% (alcohol)

Net Wt. 1000L e 33814oz



DERMONANO

alcohol gel

Product Information	luct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75751-070	
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	
WATER (UNII: 059QF0KO0R)		
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		

PANTHENOL (UNII: WV9CM0O67Z)	
TRIISO PRO PANO LAMINE (UNII: W9 EN9 DLM9 8)	

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75751-070- 04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
2	NDC:75751-070- 16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
3	NDC:75751-070- 26	1000000 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/11/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

Labeler - pghlaboratorios do brasil Ltda. (903309948)

Registrant - PGH LABORATORIOS DO BRASIL LTDA. (903309948)

Revised: 5/2020 PGHLABORATORIOS DO BRASIL LTDA.