

**HAND GEL PROLIM INSTANT HAND SANITIZER - alcohol gel**  
**Prolim Quimica Avancada 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.*

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**Drug Facts**

**Active Ingredient**

Ethyl Alcohol 70%

**Purpose**

Antiseptic

**Uses**

- Recommended for aseptic hand cleansing. This product does not replace the use of soap and water.
- Recommended for repeated use.

**Warnings**

For external use only

**When using this product**

- Keep out of eyes. In case of accidental contact, flush eyes thoroughly with water for 15 minutes.
- Avoid contact with broken skin or you have allergies to any ingredients.

**Stop use and consult a doctor if skin irritation occurs.**

**Keep out of reach of children**

- In case of accidental ingestion drink plenty of water and seek medical help or contact a Poison Control Center immediately.
- External use only.

**FLAMMABLE: Keep out of heat.**

**Directions**

- Place a small amount of product in your hand.
- Rub hands together briskly for at least 30 seconds until dry.
- Children under 6 years of age should use under adult supervision.

**Inactive Ingredients**

Water, Isopropyl Alcohol, Isopropyl Myristate, Propylene Glycol, Carbomer, DDM Hydantoin, Aminomethyl Propanol, Fragrance.

**Questions?**

555-555-5555

### Principal Display Panel

The graphic shows a hand being sanitized with gel. The text on the packaging includes:

- Hand Gel** (in a script font)
- Gel** (in a large, bold, sans-serif font)
- Prolim** (with a logo icon)
- Instant Hand Sanitizer**
- Kills 99,99% of most common germs** (in a red rounded rectangle)
- 2.7 OZ FL (80ml)** (in a blue rounded rectangle at the bottom)

The Drug Facts label contains the following information:

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- Purpose:** Antiseptic
- Uses:**
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- Warnings:**
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  - When using this product:**
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    - Avoid contact with broken skin or you have allergies to any ingredients.
  - Stop use and consult a doctor if skin irritation occurs.**
  - Keep out of reach of children.**
    - In case of accidental ingestion drink plenty of water and seek medical help or contact a Poison Control Center immediately.
    - External use only.
  - FLAMMABLE:** Keep out of heat.
- Directions:**
  - Place a small amount of product in your hand.
  - Rub hands together briskly for at least 30 seconds until dry.
  - Children under 6 years of age should use under adult supervision.
- Inactive Ingredients:** Water, Isopropyl Alcohol, Isopropyl Myristate, Propylene Glycol, Carbomer, DMDM Hydantoin, Aminomethyl Propanol, Fragrance.
- Questions?** 555-555-5555

Produced by: Prolim Quimica Avançada Ltda, Taubaté/Brazil  
Distributed by:  
(Name + Address + Phone + Fax)

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HAND GEL PROLIM  
INSTANT HAND SANITIZER  
Kills 99,99% of most common germs  
2.7 OZ FL (80ml)

HAND GEL PROLIM INSTANT HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50414-100
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	0.7 mg in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50414-100-01	60 mL in 1 BOTTLE, PLASTIC		
2	NDC:50414-100-02	80 mL in 1 BOTTLE, PLASTIC		
3	NDC:50414-100-03	100 mL in 1 BOTTLE, PLASTIC		
4	NDC:50414-100-04	200 mL in 1 BOTTLE, PUMP		
5	NDC:50414-100-05	500 mL in 1 BOTTLE, PUMP		
6	NDC:50414-100-06	1000 mL in 1 BOTTLE, PUMP		
7	NDC:50414-100-07	5000 mL in 1 BOTTLE, PLASTIC		
8	NDC:50414-100-08	1 in 1 BOX		
8		800 mL in 1 BAG		
9	NDC:50414-100-09	1 in 1 BOX		
9		1200 mL in 1 BAG		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	03/10/2010	

**Labeler** - Prolim Quimica Avancada Ltda. (907224518)**Establishment**

Name	Address	ID/FEI	Business Operations
Prolim Quimica Avancada Ltda.		907224518	manufacture

Revised: 2/2010

Prolim Quimica Avancada Ltda.