

**BURN-B GONE OTC - burn-b gone otc gel**  
**Quantum Labs 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.*

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**Burn-B Gone OTC 75g Tube**

**Active Ingredient: Allantoin 1.0%**

**Purpose:** Skin Protectant

**Uses:**

Temporarily protects skin after minor

- burns
- scrapes
- cuts
  
- Helps prevent, temporarily protects, and helps relieve chapped or cracked skin.
- Helps prevent and protect skin from the drying effects of wind and cold weather.

**Warnings:**

**For External Use Only**

**When using this product** avoid contact with eyes.

**Do not use on**

- deep or puncture wounds
- animal bites
- serious burns

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days.

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

**Directions:**

- Adults and children 2 years of age and older - Cleanse affected area thoroughly. Apply 3-4 times daily.
- Children under 2 years old - Consult a doctor.

**Other Information:** Store between 15-30C (59-86F)

**Inactive Ingredients:** Water (Aqua), SD Alcohol 40, Glycerin, Astragalus Gummifer Gum, Carbomer, Boric Acid, Disodium EDTA, Ethyl Ether, Triethanolamine, Methylparaben, Propylparaben

**Questions or comments?**

**[www.BurnBGoneOTC.com](http://www.BurnBGoneOTC.com)**

**Burn-B Gone OTC**  
**Net Wt 2.5 oz (75 g)**

**NDC 47341-002-20**

**Skin Protectant Gel for**

- Burns
- Cuts
- Scrapes

Doctor Recommended

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Allantoin 1.0%.....	Skin Protectant
<b>Uses</b> •temporarily protects skin after minor: •burns •scrapes •cuts •chapped or cracked skin •helps prevent and protect skin from the drying effects of wind and cold weather.	
<b>Warnings</b> For external use only	
<b>When using this product</b> avoid contact with eyes.	
<b>Do not use on:</b> •deep or puncture wounds •animal bites •serious burns	
<b>Stop use and ask a doctor if</b> •condition worsens •symptoms last more than 7 days or clear up and occur again within a few days.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> Adults and children 2 years and over: •clean the affected area •apply as needed 3-4 times daily •children under 2 years: ask a doctor	
<b>Other Information</b> Store at 15° to 30° C (59° to 86° F)	
<b>Inactive Ingredients</b> Water (Aqua), SD Alcohol 40, Glycerin, Astragalus Gummifer Gum, Carbomer, Boric Acid, Disodium EDTA, Ethyl Ether, Triethanolamine, Methylparaben, Propylparaben	
<b>Question or comments?</b> <a href="http://www.BurnBGoneOTC.com">www.BurnBGoneOTC.com</a>	

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Beverly Hills, CA 90211  
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**Doctor  
Recommended**

NDC 47341-002-20

**BURN-B  
GONE<sup>®</sup>**

**OTC**

Skin Protectant Gel for  
•Burns •Cuts •Scrapes

NET WT. 2.5 OZ (75 g)

## BURN-B GONE OTC

burn-b gone otc gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:47341-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	0.75 g in 75 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Tragacanth</b> (UNII: 2944357O2O)	
<b>Carbomer Homopolymer Type C</b> (UNII: 4Q93RCW27E)	
<b>Boric Acid</b> (UNII: R57ZHV85D4)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Ether</b> (UNII: 0F5N573A2Y)	
<b>Trolamine</b> (UNII: 9O3K93S3TK)	
<b>Methylparaben</b> (UNII: A218C7H9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47341-002-20	75 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/10/2010	

**Labeler** - Quantum Labs LLC (932206126)

**Registrant** - Quantum Labs LLC (932206126)

## Establishment

Name	Address	ID/FEI	Business Operations
Quantum Labs LLC		932206126	manufacture