

**BURN-B GONE OTC - allantoin gel**  
**DeWitt Laboratories, Inc**

*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)

**Doctor Recommended**

**BURN-B GONE OTC™**

Skin Protectant Gel for  
• Burns • Cuts • Scrapes

**NET WT. 2.5 OZ (75 g)**

| Drug Facts   |                 |
|--|-----------------|
| <b>Active Ingredient</b>   | <b>Purpose</b>  |
| Allantoin 1.0%   | Skin Protectant |
| <b>Uses</b> • Helps help to protect skin after minor burns • scrapes • cuts • chapped or cracked skin • helps protect and protect skin from the drying effects of wind and cold weather.     |                 |
| <b>Warnings</b><br>For external use only.  |                 |
| <b>When using this product</b> avoid contact with eyes.  |                 |
| <b>Do not use on</b> • Wet or puncture wounds, second degree • third degree burns.   |                 |
| <b>Stop use and ask a doctor if</b> • Irritation persists • 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><br>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><br>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><br><a href="http://www.BurnBGoneOTC.com">www.BurnBGoneOTC.com</a>   |                 |

Distributed by  
DR. WITT LABORATORIES, INC.  
Beverly Hills, CA 90211  
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**BURN-B GONE OTC**

allantoin gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:51483-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>                                     | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z) | Allantoin                | 0.75 g in 75 g  |

**Inactive Ingredients**

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

**Packaging**

| # | <b>Item Code</b> | <b>Package Description</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:51483-002-20 | 75 g in 1 TUBE             |                             |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part347   | 06/01/2010                  |                           |

**Labeler** - DeWitt Laboratories, Inc (040211711)**Registrant** - Quantum Labs LLC (932206126)**Establishment**

| <b>Name</b>      | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|------------------|----------------|---------------|----------------------------|
| Quantum Labs LLC |                | 932206126     | manufacture                |