

## **DIABETIC WOUND GEL PROFESSIONAL- allantoin gel**

**Lavior 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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### **Active Ingredients**

Allantoin 0.5%.....Skin Protectant

### **Purpose**

Skin Protectant

### **Uses**

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

### **Warnings**

**For external use only**

### **When using this product**

- avoid contact with eyes

### **Stop use and ask a doctor if**

- condition worsens
- symptoms last more than 7 days, clear up and occur again within a few days

### **Do not use**

- deep or puncture wounds
- animal bites
- serious burns

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

apply a thin layer 1 to 2 times daily, or as directed by a doctor

### **Other information**

store at room temperature

### **Inactive Ingredients**

Water/Aqua/Eau, Glycerin, Inula Viscosa Flower/Leaf/Stem Extract, Xanthan Gum, Phenoxyethanol, Propanediol, Tocopheryl Acetate, Ethylhexylglycerin, Sodium Gluconate, Citric Acid, Sodium Hyaluronate

### **Questions?**

Call toll free 1844-474-2552 or visit [www.lavior.com](http://www.lavior.com)



## DIABETIC WOUND GEL PROFESSIONAL

allantoin gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71521-035 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN         | 1 g in 100 g |

### Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| PHENOXYETHANOL (UNII: HIE492ZZ3T)             |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |          |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH)         |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                |          |
| PROPANEDIOL (UNII: 5965N8W85T)                |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)         |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)    |          |
| SODIUM GLUCONATE (UNII: R6Q3791S76)           |          |
| DITTRICHIA VISCOSA WHOLE (UNII: 3SYW69FH88)   |          |

### Product Characteristics

|          |  |              |  |
|----------|--|--------------|--|
| Color    |  | Score        |  |
| Shape    |  | Size         |  |
| Flavor   |  | Imprint Code |  |
| Contains |  |              |  |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71521-035-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/31/2021           |                    |



## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 03/31/2021           |                    |

**Labeler** - Lavior Inc (080685327)