

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.

Active Ingredient

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, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Propanediol, Tocopheryl Acetate, Ethylhexylglycerin, Sodium Gluconate, Citric Acid, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate

Questions?

Call toll free 1-844-474-2552 or visit www.lavior.com



WOUND GEL PROFESSIONAL

allantoin gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71521-038 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 0.5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: VR1WPI7EW8) | |
| DITTRICHIA VISCOSA WHOLE (UNII: 3SYW69FH88) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71521-038-50 | 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)