

**WINTER SKIN PROTECTANT- zinc oxide, allantoin ointment  
Biomin 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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**Winter + Skin Protectant**

**DRUG FACTS**

**Active Ingredients**

Zinc Oxide 20.00%

Allantoin 2%

**Purpose**

Sunscreen

Skin Protectant

**Uses:**

Temporarily protects and helps relieve chapped or chafed skin. Helps prevent and protect from the drying effects of wind and cold weather.

**Warnings:**

**For external use only.**

**Do not use**

- on damaged or broken skin.
- Do not use deep or puncture wounds animal bites serious burns.

**Stop use and ask a doctor**

- If rash occurs conditions worsens symptoms last more than 7 days or clear up again within a few days.

**When using this product**

- Keep out of eyes.
- Rinse with water to remove.

**Keep out of reach of children.**

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

## Directions:

- Apply as needed.
- Children under 6 months of age: Ask a doctor.

## Inactive Ingredients:

Cocos Nucifera (Coconut) Oil, Cera Alba (Beeswax), Calendula Officinalis (Calendula Flower) Infused in Simmondsia Chinensis (Jojoba Oil), Tocopherol (Vitamin E)

## Other Information:

Protect this product from excessive heat and direct sun.

## Package Labeling:



## WINTER SKIN PROTECTANT

zinc oxide, allantoin ointment

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:82177-001 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION       | 200 mg in 1 mL |
| <b>ALLANTOIN</b> (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)    | ALLANTOIN         | 20 mg in 1 mL  |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| COCONUT OIL (UNII: Q9L0073W7L)                  |          |
| YELLOW WAX (UNII: 2ZA36H0S2V)                   |          |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) |          |
| JOJOBA OIL (UNII: 724GKU717M)                   |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                   |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82177-001-00 | 120 mL in 1 JAR; Type 0: Not a Combination Product | 07/01/2022           |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 07/01/2022           |                    |

**Labeler** - Biomin LLC. (105075828)

Revised: 6/2022

Biomin LLC.