# LANTISEPTIC SKIN PROTECTANT- lanolin cream Summit Industries, 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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#### **Lantis eptic Skin Protectant Drug Facts**

### **Active Ingredient**

Lanolin USP 50%

#### **Purpose**

Skin Protectant

#### Uses

- Helps prevent and treat diaper dermatitis.
- Protects chafed skin or minor skin irritations due to incontinence and helps seal out wetness.

#### **Warnings**

- For external use only.
- Avoid contact with eyes.
- Do not apply to deep or puncture wounds.
- If condition worsens, or does not improve within 7 days, consult a doctor.
- If swallowed, get medical help or contact a Poison Control Center right away.
- Keep out of reach of children.

#### Directions

- Gently cleanse and dry area.
- Apply liberally to affected area as needed.

# Other information

Store at 20-25°C (68-77°F)

## **Inactive ingredients**

Beeswax (yellow wax), Fragrance, HEEDTA, Lanolin Alcohol, Mineral Oil, Oxyquinoline, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate

If you have questions or comments, call

800-241-6996 or visit

www.Lantiseptic.com

SUMMIT INDUSTRIES, INC

Lantiseptic Division

PO BOX 7329

### Image of representative container

SP400g.jpg





SP\_130.jpg



#### LANTISEPTIC SKIN PROTECTANT

lanolin cream

| Product Information     |                      |                    |                |
|-------------------------|----------------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:12090-0019 |
| Route of Administration | TOPICAL              | DEA Schedule       |                |

| Active Ingredient/Active Moiety |                   |               |  |
|---------------------------------|-------------------|---------------|--|
| Ingredient Name                 | Basis of Strength | Strength      |  |
| LANOLIN (LANOLIN)               | LANOLIN           | 500 mg in 1 g |  |

| Inactive Ingredients                       |          |
|--|----------|
| Ingredient Name                            | Strength |
| YELLOW WAX                                 |          |
| HYDRO XYETHYLETHYLENEDIAMINETRIACETIC ACID |          |
| LANOLIN ALCOHOLS                           |          |
| MINERAL O IL                               |          |
| OXYQUINOLINE                               |          |
| PETROLATUM                                 |          |

| WATER                 |  |
|-----------------------|--|
| SODIUM BORATE         |  |
| SORBITAN SESQUIOLEATE |  |

| Pá | Packaging        |                     |                      |                    |
|----|------------------|---------------------|----------------------|--------------------|
| #  | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1  | NDC:12090-0019-6 | 5 g in 1 PACKET     |                      |                    |
| 2  | NDC:12090-0019-1 | 14.2 g in 1 JAR     |                      |                    |
| 3  | NDC:12090-0019-2 | 70 g in 1 TUBE      |                      |                    |
| 4  | NDC:12090-0019-3 | 113 g in 1 JAR      |                      |                    |
| 5  | NDC:12090-0019-4 | 130 g in 1 JAR      |                      |                    |
| 6  | NDC:12090-0019-5 | 400 g in 1 JAR      |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part347                                  | 12/30/2009           |                    |
|                         |  |                      |                    |

# Labeler - Summit Industries, Inc. (003279189)

# Registrant - Summit Industries, Inc. (003279189)

| Establishment           |         |           |                         |
|-------------------------|---------|-----------|-------------------------|
| Name                    | Address | ID/FEI    | Business Operations     |
| Summit Industries, Inc. |         | 003279189 | manufacture(12090-0019) |

Revised: 1/2013 Summit Industries, Inc.