

LANTISEPTIC DRY SKIN THERAPY- lanolin cream

Dermarite Industries 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.

Lantisepic by Dermarite Daily Care Skin Protectant

Drug Facts

Active Ingredient

Lanolin USP 30%

Purpose

Skin Protectant

Uses

- Temporarily protects minor cuts, scrapes, and burns
- Helps prevent and temporarily protects chafed, chapped, or cracked skin.

Warnings

• **For external use only.** • **Avoid contact with eyes.** • In case of contact, flush thoroughly with water.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- conditions worsen
- symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

In case of accidental ingestion contact a physician or Poison Control Center right away.

Keep out of reach of children.

Directions

Apply liberally to affected area as needed or as directed by a physician.

Other Information

- Store at room temperature (59-86°F)
- You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

Inactive Ingredients

Water, Mineral Oil, Petrolatum, Cera Alba, Sodium Borate, DMDM Hydantoin, Sorbitan Sesquioleate, Lanolin Alcohol, Disodium EDTA


Questions or Comments?

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

Package Labeling:

Room # _____
Patient Name _____

NDC 61924-710-14



Lantiseptic
by DermaRite

LANOLIN
ENRICHED™

30% Lanolin

Moisturizes & protects
irritated skin

REORDER #LS0710

Daily Care
SKIN PROTECTANT

Net Wt. 397 g (14 oz.)

Drug Facts

| | |
|--|-----------------------------------|
| Active ingredient Lanolin USP 30% | Purpose Skin protectant |
| Uses ■ Temporarily protects minor cuts, scrapes, and burns. ■ Helps prevent and temporarily protects chafed, chapped, or cracked skin. | |
| Warnings For external use only. Avoid contact with eyes. In case of contact, flush thoroughly with water. Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns. Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days. Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away. | |


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DermaRite
MADE IN THE USA
DermaRite Industries LLC • 7777 West Side Avenue
North Bergen, NJ 07047 • www.dermaRite.com



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LANTISEPTIC DRY SKIN THERAPY

lanolin cream

| Product Information | | | | |
|--|------------------|---|----------------------|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61924-710 | |
| Route of Administration | TOPICAL | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H) | | LANOLIN | 300 mg in 1 g | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| LANOLIN ALCOHOLS (UNII: 884C3FA9HE) | | | | |
| MINERAL OIL (UNII: T5L8T28FGP) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| SODIUM BORATE (UNII: 91MBZ8H3QO) | | | | |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61924-710-14 | 397 g in 1 JAR; Type 0: Not a Combination Product | 12/25/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 12/25/20 18 | |

Labeler - Dermalite Industries LLC (883925562)

Registrant - Dermalite Industries LLC (883925562)

Revised: 1/2020

Dermalite Industries LLC