LANTISEPTIC BY DERMARITE 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.

Lantiseptic by Dermarite Dry Skin Therapy

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 our of reach of children. In case of accidental ingestion contact a physician or Poision 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:

LANTISEPTIC BY DERMARITE DRY SKIN THERAPY

lanolin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-504
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**
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
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:61924-504-14	14.2 g in 1 PACKET; Type 0: Not a Combination Product	12/25/2018	
2	NDC:61924-504-04	113 g in 1 TUBE; Type 0: Not a Combination Product	12/25/2018	
3	NDC:61924-504-05	5 g in 1 PACKET; 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	12/25/2018	

Labeler - Dermarite Industries LLC (883925562)

Registrant - Dermarite Industries LLC (883925562)

Revised: 1/2020 Dermarite Industries LLC