LANODERM- otc skin protectant drug products ointment
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.

DRUG LISTING: LANODERM

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 punctured wounds.
- **Stop use and ask doctor if** condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

Warnings:

- **Keep out of reach of children.** In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions:

Apply liberally to affected area as needed or as directed by 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:

Cera Alba, Disodium EDTA, DMDM Hydantion, Lanolin Alcohol, Methylparaben, Mineral Oil, PEG-30 Dipolyhydroxydstearate, Petrolatum, Propylene Glycol, Propylparaben, Sodium Borate, Sodium Chloride, Water

Questions?

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

Lanoderm Package Label Principal Display Panel

LANODERM

otc skin protectant drug products ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-232
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	0.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
WHITE WAX (UNII: 7G1J5DA97F)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-232-04	113 g in 1 TUBE; Type 0: Not a Combination Product	04/16/2012	
2	NDC:61924-232-05	5 g in 1 PACKET; Type 0: Not a Combination Product	04/16/2012	
3	NDC:61924-232-15	15 g in 1 PACKET; Type 0: Not a Combination Product	04/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/16/2012	

Labeler - Dermarite Industries LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
Dermarite Industries LLC		883925562	manufacture(61924-232)