LINCOFIX- lanolin ointment
Lincoln Pharmaceuticals Ltd.

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.

Active Ingredient

Lanolin 22%

Purpose

Skin Protectant

Uses

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

Warnings

FOR EXTERNAL USE ONLY

When using this product

- Avoid contact with eyes
- If contact occurs, flush with water

Stop use and ask a doctor if

- condition worsens
- symptoms last more than seven days or clear up and occur again within seven days

Do not use on

- deep or puncture wounds
- lacerations
- animal bites
- serious burns

Keep out of reach of children

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

Directions

Apply as needed to clean skin twice daily or more often if necessary

- For Children under 6 months ask a doctor

Inactive Ingredients

Aluminium Hydroxide, Alpha Tocopherol Acetate(Vitamin E), Calcium carbonate, Cholecalciferol (Vitamin D3), Citric Acid,Corn Oil, Ethylparaben, Lanolin, Magnesium Hydroxide, Methylparaben,

Sodium Chloride, Sodium laureth Sulfate, Petrolatum, Vitamin A Palmitate, Water, Zinc Chloride

LINCOFIX

lanolin ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69636-8050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	22 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
CORN OIL (UNII: 8470G57WFM)	
ETHYLPARABEN (UNII: 14255EXE39)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
PETROLATUM (UNII: 4T6H12BN9U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69636-8050-2	113 g in 1 TUBE; Type 0: Not a Combination Product	10/06/2016	
2	NDC:69636-8050-3	113 g in 1 JAR; Type 0: Not a Combination Product	10/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/06/2016	

Labeler - Lincoln Pharmaceuticals Ltd. (915839373)

Revised: 10/2016 Lincoln Pharmaceuticals Ltd.