LINCOLN- zinc oxide cream
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

Zinc Oxide (3.8% w/w)

PURPOSE

Skin Protectant

USES

- helps treat and prevent diaper rash
- temporarily protects minor cuts, scrapes, burns
- dries the oozing and weeping of poison ivy, poison oak, poison sumac

WARNINGS

FOR EXTERNAL USE ONLY

When using this product

- Do not get into the eyes

Stop use and ask a doctor

- If condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

Keep out of reach of children

- if swallowed, get medical help or contact the Poison Control Center right away

DIRECTIONS

- change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged
- for poison ivy, oak, and sumac
- apply ointment liberally as needed

OTHER INFORMATION

- store at room temperature 15°C-30°C (59-86 F)
- avoid excessive heat

INACTIVE INGREDIENTS

aloe vera leaf, alpha-tocopherol, ceteth-10, cetostearyl alcohol, cetyl alcohol, cholecalciferol, glycerin, lanolin, lavender, methyl paraben, mineral oil, paraffin, petrolatum, phenoxyethanol, polyethylene glycol 6000, polysorbate 60, propylparaben sodium, steareth-20, trolamine, vitamin A, water, FD&C Yellow No. 5, D&C Red No. 21

PACKAGE LABEL

LINCOLN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69636-3066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
LANOLIN (UNII: 7EV65EAW6H)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	

STEARETH-20 (UNII: L0Q8IK9E08)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TROLAMINE (UNII: 9O3K93S3TK)	
VITAMIN A (UNII: 81G40H8B0T)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69636-3066-4	99.2 g in 1 TUBE; Type 0: Not a Combination Product	01/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/10/2017	

Labeler - Lincoln Pharmaceuticals Ltd. (915839373)

Revised: 1/2017 Lincoln Pharmaceuticals Ltd.