LINCOSHIELD- zinc oxide 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

Zinc Oxide 3.8%

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash, incontinence or exposure to feces and urine
- Protects skin against irritation due to such rash
- Helps protect skin from exposure to wetness

Warnings

FOR EXTERNAL USE ONLY

When using this product

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

Stop use and ask a doctor if

- condition worsens or doesn't improve within seven days

Keep out of reach of children

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

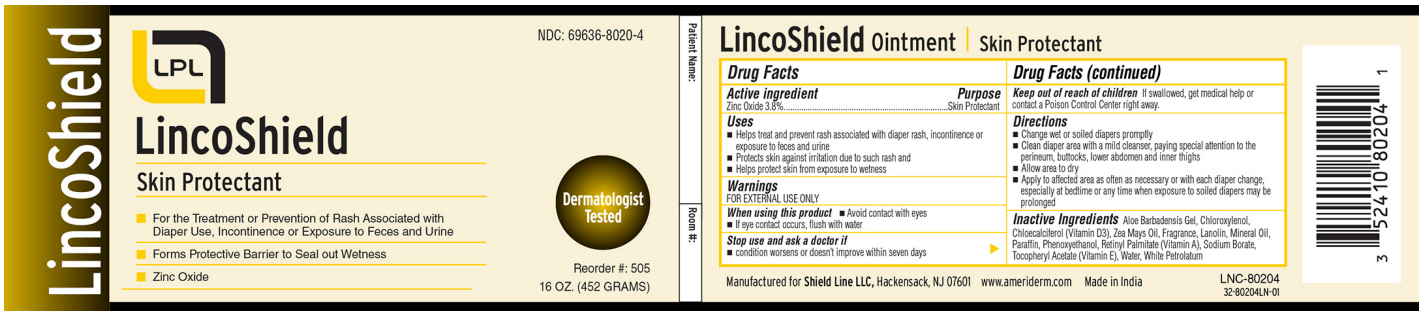
Directions

- Change wet or soiled diapers promptly
- Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs
- Allow area to dry
    - Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to

soiled diapers may be prolonged

Inactive Ingredients

Aloe Barbadensis Gel, Chloroxylenol, Cholecalciferol (Vitamin D3), Zea Mays Oil, Fragrance, Lanolin, Mineral Oil, Paraffin, Phenoxyethanol, Retinyl Palmitate (Vitamin A), Sodium Borate, Tocopherol Acetate (Vitamin E), Water, White Petrolatum



LINCOSHIELD

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69636-8020
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
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69636-8020-4	452 g in 1 JAR; Type 0: Not a Combination Product	10/06/2016	
2	NDC:69636-8020-0	100 g in 1 TUBE; 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)

Establishment

Name	Address	ID/FEI	Business Operations
Lincoln Pharmaceuticals Ltd.		915839373	manufacture(69636-8020)

Revised: 10/2016 Lincoln Pharmaceuticals Ltd.