ZINC OXIDE CREAM- zinc oxide cream Emerging Pharma, 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.

Zinc Oxide Cream

Active ingredient

Zinc Oxide 22%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect skin from wetness.

Warnings

For external use only

When using this product do not get into eyes

Stop use and ask a doctor if

- conditions worsen
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry.
- Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information

• store at 20-30°C (68-86°F)

Inactive ingredients

aloe barbadensis leaf juice, caprylyl glycol, ceteareth- 20, cetyl alcohol, chlorphenesin, glycerine, mineral oil, phenoxyethanol, purified water, stearyl alcohol, tocopheryl acetate (vitamin E), white petrolatum

Questions?

Call 1-844-221-7294.

Manufactured for

Emerging Pharmaceuticals New Jersey, USA

Package Label

NDC 70050-100-04 NET WT: 4 oz (113 grams)



ZINC OXIDE CREAM

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70050-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CHLORPHENESIN (UNII: 1670DAL4SZ)		
GLYCERIN (UNII: PDC6A3C0OX)		
MINERAL OIL (UNII: T5L8T28FGP)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
WHITE PETROLATUM (UNII: B6E5W8RQJ4)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70050-100- 04	113 g in 1 JAR; Type 0: Not a Combination Product	05/01/2022	

Marketing In	rketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	05/01/2022		

Labeler - Emerging Pharma, LLC (079862083)

Revised: 5/2022 Emerging Pharma, LLC