

DIAPER- zinc oxide ointment
Medek Laboratories Inc.

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 Facts

Active Ingredients

Purpose

Zinc Oxide 12.8%.....Skin Protectant

Purpose

Skin Protectant

Warnings

FOR EXTERNAL USE ONLY

When using this product

When using this product keep out of eyes.

Stop use and ask a doctor if

Stop use and ask a doctor if condition worsens or does not improve after 7 days

Keep out of reach of children

Keep out of reach of children.

Other Information

protect this product from excessive heat and direct sun

Inactive Ingredients

Petrolatum, corn starch, anhydrous lanolin, stearyl alcohol, beeswax, camellia sinensis leaf extract, tocopheryl acetate, sunflower seed extract, sorbitan oleate, bisabolol, cholesterol

Indications

Uses

Help heal and prevent diaper rash

Protects chafed skin due to diaper rash and helps protect wetness

Do Not Use

Discontinue use if irritation occurs.

Ask a doctor

Ask a doctor if condition worsens

Directions

change wet and soiled diapers promptly

cleanse the diaper area

allow to dry

apply ointment liberally as often as necessary with each diaper change and anytime when exposure to wet diapers may be prolonged

dosage

apply ointment liberally as often as necessary with each diaper change and anytime when exposure to wet diapers may be prolonged

image of label



Uses

- helps heal and prevent diaper rash · protects chafed skin due to diaper rash and helps protect from wetness

Warnings For external use only.

When using this product · do not get into eyes

Stop use and ask a doctor if · condition worsens or does not improve after 7 days

Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center immediately.

Directions · change wet and soiled diapers promptly · cleanse the diaper area · allow to dry · apply ointment liberally as often as necessary with each diaper change and anytime when exposure to wet diapers may be prolonged

Inactive Ingredients Petrolatum, Corn Starch, Anhydrous Lanolin, Stearyl Alcohol, Beeswax, Camellia Sinensis Leaf Extract, Tocopheryl Acetate, Helianthus Annuus (Sunflower) Seed Extract, Sorbitan oleate, Bisabolol, Cholesterol.

Questions? Call toll-free 1-844-75-medek (6335)



Distributed by: MeDek Laboratories INC.

DIAPER

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71969-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	21.76 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LANOLIN (UNII: 7EV65EAW6H)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
CANDELILLA WAX (UNII: WL0328HX19)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
TOCOL ACETATE (UNII: 37Z972M0N0)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
BISABOLOL OXIDE A (UNII: 16AE65F94Y)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71969-111-01	170 g in 1 JAR; Type 0: Not a Combination Product	03/08/2018	
2	NDC:71969-111-02	1 in 1 PACKAGE	04/09/2018	
2		57 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/08/2018	

