

## **ATOPALM DIAPER RASH - zinc oxide cream**

**NeoPharm Co., 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.*

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### **ATOPALM Diaper Rash Cream**

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#### **Active Ingredient**

Zinc Oxide 10%

#### **Purpose**

Skin Protectant

#### **Uses**

- Helps treat and prevent diaper rash
- Protects chafed skin and minor irritation associated with diaper rash
- Helps seal out wetness.

#### **Warnings**

**For external use only.**

#### **When using this product**

- avoid contact with the eyes.

#### **Stop use and ask a doctor if**

- Conditions worsen
- symptoms last more than seven days
- symptoms clear up and occur within a few days.

#### **Keep out of reach of children.**

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

#### **Directions**

- Change wet and soiled promptly
- Cleanse the diaper area and allow to dry.
- Apply cream liberally, as often as necessary, with each diaper change, especially at bedtime or before any prolonged exposure to wet diapers.

#### **Other Information**

- store at 15 degrees - 30 degrees C (59 degrees - 86 degrees F)

- see carton flap or tube crimp for lot number and expiration date

## Questions or information call toll free:


1-855-ATOPALM

### Inactive Ingredients

WATER, WHITE PETROLATUM, LIGHT MINERAL OIL, SORBITAN SESQUILEATE, WHITE BEESWAX, TALC, STEARIC ACID, DIMETHICONE, ALOE VERA GEL, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, CHOLESTEROL, PANTHENOL, TOCOPHERYL ACETATE, BENZYL ALCOHOL, SODIUM BENZOATE, FRAGRANCE.

### ATOPALM Diaper Rash Cream 2oz (51141-0237-2)

<b>ATOPALM™</b> <b>DIAPER RASH CREAM</b> <i>Provides long lasting relief while moisturizing with US Patented Pseudoceramide.  Helps calm, protect and soothe irritation associated with diaper rash.</i>		
<b>PROVIDES LONG LASTING PROTECTION</b>		
<b>ATOPALM™</b> <b>DIAPER RASH CREAM</b> Net Wt. 2 oz / 57 g	 Contains Vitamin E Acetate – Paraben Free	<b>ATOPALM™</b> <b>DIAPER RASH CREAM</b> 10% Zinc Oxide
<i>Skin moisturizing formula based upon US Patented Pseudoceramide</i>		

<b>Drug Facts</b> <b>Active Ingredient</b> ..... <b>Purpose</b> Zinc Oxide 10% ..... Skin Protectant <b>Uses</b> ■ Helps treat and prevent diaper rash ■ protects chafed skin and minor irritation associated with diaper rash ■ helps seal out wetness. <b>Warnings</b> For external use only. <b>When using this product</b> ■ avoid contact with the eyes. <b>Stop use and ask a doctor if</b> ■ Conditions worsen ■ symptoms last more than seven days ■ symptoms clear up and occur within a few days.	<b>Drug Facts (continued)</b> Keep out of reach of children. If swallowed, get medical help immediately or contact a Poison Control Center right away. <b>Directions</b> ■ 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 before any prolonged exposure to wet diapers. <b>Other Information</b> ■ store at 15°–30°C (59°–86°F) ■ see carton flap or tube crimp for lot number and expiration date <b>Questions or information call toll free:</b> 1-855-ATOPALM	Batch/Lot # / Exp. Date
<b>Drug Facts (continued)</b> <b>Inactive Ingredients</b> WATER, WHITE PETROLATUM, LIGHT MINERAL OIL, SORBITAN SESQUILEATE, WHITE BEESWAX, TALC, STEARIC ACID, DIMETHICONE, ALOE VERA GEL, MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA, CHOLESTEROL, PANTHENOL, TOCOPHERYL ACETATE, BENZYL ALCOHOL, SODIUM BENZOATE, FRAGRANCE. US Patent # US 6221371B1 Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07769 Made in Korea	 8 57811 00237 8	

**PROVIDES LONG LASTING PROTECTION**

# ATOPALM™

## DIAPER RASH CREAM

Contains Vitamin E Acetate – Paraben Free

Net Wt. 2 oz/57 g



**Skin moisturizing formula based upon US Patented Pseudoceramide**

**Active Ingredient** Zinc Oxide 10%

**Uses** Helps treat and prevent diaper rash ■ protects chafed skin and minor irritation associated with diaper rash ■ helps seal out wetness.

**Warnings: For external use only.**

Avoid contact with the eyes. If condition worsens or does not improve in 7 days or if symptoms clear up and occur again within a few days, consult a doctor.

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

**Directions** ■ Change wet and soiled diapers promptly ■ cleanse the diaper area ■ 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 15° to 30°C (59° to 86°F).

**Questions or information call toll free:** 1-855 ATOPALM

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea #75727

## ATOPALM DIAPER RASH

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51141-0237
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA</b> (UNII: 1211AIM8G7)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0237-2	57 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	06/07/2012	

**Labeler** - NeoPharm Co., Ltd (965502912)

**Registrant** - NeoPharm Co., Ltd (965502912)

### Establishment

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd		631101883	manufacture

Revised: 6/2012

NeoPharm Co., Ltd