

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

**Natureplex 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.*

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**Natureplex™**

### **Drug Facts**

#### **Active ingredient**

Zinc Oxide 40%

#### **Purpose**

Skin Protectant

#### **Uses**

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

#### **Warnings**

**For external use only.**

**Avoid contact with eyes.**

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

- condition worsens
- 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: 800-222-1222.

#### **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, especially at bedtime or any time when exposure to wet diapers may be prolonged

#### **Other information**

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

#### **Inactive ingredients**

aloe barbadensis leaf juice, BHA, cetyl alcohol, coconut butter, corn starch, fragrance, hydroxyethylcellulose, lanolin, methylparaben, mineral oil, petrolatum, polysorbate 20, purified water, shea butter

**Questions or comments?**

**866-323-0107 or [www.natureplex.com](http://www.natureplex.com)**

**PRINCIPAL DISPLAY PANEL - 42.5 g Tube Box**

Natureplex™

Diaper Rash Cream  
40% Zinc Oxide with Aloe  
for  
babies

NET WT. 1.5 Oz. (42.5g)

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67234-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	400 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCOA BUTTER (UNII: 512OYT1CRR)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6HI2BN9U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0K00R)	
SHEA BUTTER (UNII: K49155WL9Y)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-001-01	1 in 1 BOX	01/02/2005	
1		42.5 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part347	01/02/2005	

**Labeler** - Natureplex LLC (062808196)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Natureplex LLC		062808196	MANUFACTURE(67234-001)