

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.

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

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)

NDC 67234-001-01

Natureplex



Diaper Rash Cream

for babies

40% Zinc Oxide with Aloe

- Soothes Burning • Prevents Diaper Rash • Protects Skin



* Compare to the active ingredients of Desitin®



Promotes Healing

- Hypoallergenic • Relieves Chafing



31298
V02

Natureplex



Diaper Rash Cream

40% Zinc Oxide with Aloe for babies

NET WT. 1.5 Oz. (42.5g)



Natureplex

Diaper Rash Cream

*This product is not manufactured by or distributed by Pfizer Consumer Healthcare, the distributor of Desitin®.



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NATUREPLEX, Olive Branch, MS 38654



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Questions or comments? 866-923-0107 or www.natureplex.com
Active Ingredients Zinc Oxide 40%, Aloe Vera, BHA, Cetyl Alcohol, Coconut Butter, Corn Starch, Fragrance, Hydroxyethylcellulose, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Polyethylene Glycol, Purified Water, Shea Butter
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 ■ prolonged
Directions ■ apply liberally as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be allowed to dry ■ cleanse the diaper area ■ change wet and soiled diapers promptly
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
Uses ■ helps treat and prevent diaper rash ■ protects chafed skin due to diaper rash and helps seal out these
Drug Facts Zinc Oxide 40% Skin Protectant Purpose



Diaper Rash Cream for babies

Natureplex

zinc oxide cream

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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

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

Labeler - Natureplex LLC (062808196)

Establishment

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

