

## **HYLANDS NATURALS DIAPER RASH CREAM- zinc oxide cream**

### **Hylands**

*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.*

-----

### **Hylands Naturals Diaper Rash Cream**

#### **Drug Facts**

Active ingredients Purpose

Zinc Oxide 10%..... skin protectant

#### **Purpose**

Skin protectant

#### **Uses**

- Helps treat and prevent diaper rash.
- Protects chafed skin associated with 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.
- 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.

#### **Inactive ingredients**

Organic Aloe (Aloe Barbadensis) Leaf Extract, Organic Beeswax, Organic Calendula Officinalis Flower Extract, Organic Castor (Ricinus Communis) Seed Oil, Organic Matricaria (Chamomilla Recutita) Flower Extract, Organic Sunflower (Helianthus Annuus) Seed Oil, Tocopherol.

**Questions?** [www.hylands.com](http://www.hylands.com)  
or [care@hylands.com](mailto:care@hylands.com)

# Package Labeling

Hylands

NATURALS

• baby •

DIAPER

RASH

CREAM

Helps Soothe,  
Treat and Prevent

Diaper Rash

PEDIATRICIAN

TESTED

**DO NOT USE IF TAMPER-EVIDENT SEAL  
IS BROKEN OR MISSING.**

Manufactured for:

Hyland's, Inc.

Los Angeles, CA 90061

[www.hylands.com](http://www.hylands.com)

Certified Organic

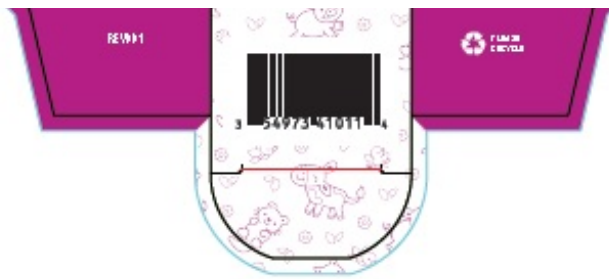
by Oregon Tilth

P-012459\_A

© 2022 PII

GRAIN





Tube length 4-7/16"  
Coat Are

res

<b>HYLANDS NATURALS DIAPER RASH CREAM</b>			
zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-4101
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	10.0 g in 100 g
<b>Inactive Ingredients</b>			

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>MATRICARIA CHAMOMILLA FLOWERING TOP</b> (UNII: 3VNC7T6Z02)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-4101-1	1 in 1 BOX	12/05/2022	
1		85 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	12/05/2022	

**Labeler** - Hylands (008316655)

Revised: 6/2023

Hylands