

NATURALS BY SAFETY 1ST- zinc oxide ointment

Dorel Juvenile Group

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.

Naturals™ by Safety 1st® Diaper Rash Cream

Active ingredient

Zinc Oxide 10%

Purpose

Skin Protectant

Uses

- Helps improve the skin condition where diaper rash or redness is present.

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

- remove safety seal, do not use if broken
- 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

Other information

- store at 59° to 86° F (15° to 30° C)

Inactive ingredients

Water (Aqua), Canola Oil, Ricinus Communis (Castor) Seed Oil, Stearic Acid, Glycerin, Cetyl Alcohol, Beeswax, Cetearyl Glucoside, Benzyl Alcohol, Sodium Hydroxide, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Fragrance.

Principal Display Panel

naturals™ by Safety 1st® Diaper Rash Cream

Pediatrician tested · Naturally mild & effective

Developed with safety in mind

99.09% Natural

Bath time experts at Safety 1st worked with parents to develop a natural baby bath & body care line that you can count on to be Safety 1st safe & naturally effective.

- No parabens, phthalates, formaldehyde or dyes
- No harmful chemicals/preservatives

Manufactured for Dorel Juvenile Group.

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2525 State Street, Columbus, IN 47201

www.djgusa.com (877)657-9545

www.safety1st.com/babycare

Made in CANADA

Drug Facts
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Dorel **NATURAL PRODUCTS ASSOCIATION CERTIFIED** **HDPE** **NOT TESTED ON ANIMALS**

Diaper Rash Cream #DG001
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naturals™
 by **Safety 1st®**
Diaper Rash Cream
 Pediatrician tested • Naturally mild & effective
 Developed with safety in mind

99.09% Natural
3 FL OZ - 88 mL
 P/N 43130017

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 2525 State Street, Columbus, IN 47201
 www.djgusa.com (877) 657-9545
 www.safety1st.com/babycare Made in CANADA.

Tube Label

NATURALS BY SAFETY 1ST

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50428-3001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.8 g in 88 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CANOLA OIL (UNII: 331KBJ17RK)	
CASTOR OIL (UNII: D5340Y2I9G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50428-3001-8	6 in 1 CARTON		
1	NDC:50428-3001-7	88 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2010	

Labeler - Dorel Juvenile Group (118841501)

Revised: 11/2012

Dorel Juvenile Group