

GRAHAMS NATURAL DIAPER RASH- zinc oxide cream

Grahams Natural Alternatives Pty 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.

ACTIVE INGREDIENT

Zinc Oxide 12%

PURPOSE

Skin Protectant

Keep out of reach of children

Uses and Indications

For the relief of diaper rash, minor cuts and burns

Directions

Apply cream, liberally, and as often as necessary to dry skin, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Warnings

For external use only

Avoid contact with eyes. If any adverse reaction develops, stop use, and contact a physician.

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Questions

www.itchy.net.au

Made in Australia

Grahams Natural Alternatives Pty Ltd

7 Palings Crt, Nerang, QLD 4211 Australia

Inactive Ingredients

Purified Water, Betaine, Glycerin, Cetearyl Alcohol, Glyceryl Stearate SE, Coco-Caprylate, Prunus Amygdalus Dulcis (Sweet Almond) Oil), Helianthus Annuus (Sunflower) Seed Oil, Butyrospermum Parkii (Shea Butter), Beeswax, Caprylic/Capric Triglyceride, Sodium Stearoyl Glutamate, Jojoba Oil, Xanthan Gum, Chamomile Extract, Calendula Extract, Tocopherol Acetate, Phenoxyethanol, Capryl Glycol

Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Zinc Oxide 12%	Skin Protectant
USES: Diaper rash, minor cuts and burns.	
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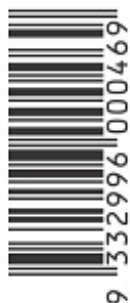
Diaper Rash Cream

especially formulated for babies & children

100g/3.5oz



Manufacturer:
Grahams Natural
Alternatives Pty Ltd
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Australia
www.itchy.net.au



GRAHAMS NATURAL DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42387-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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JOJOBA OIL (UNII: 724GKU717M)
CHAMOMILE (UNII: FGL3685T2X)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
WATER (UNII: 059QF0KO0R)
YELLOW WAX (UNII: 2ZA36H0S2V)
GLYCERIN (UNII: PDC6A3C0OX)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
COCO-CAPRYLATE (UNII: 4828G836N6)
ALMOND OIL (UNII: 66YXD4DKO9)
SUNFLOWER OIL (UNII: 3W1JG795YI)
SHEA BUTTER (UNII: K49155WL9Y)
XANTHAN GUM (UNII: TTV12P4NEE)
CALENDULA ARVENSIS LEAF (UNII: 3U3U118F2L)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
SODIUM LEVULINATE (UNII: VK44E1MQU8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42387-135-01	73 g in 1 TUBE; Type 0: Not a Combination Product	07/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/21/2016	

Labeler - Grahams Natural Alternatives Pty Ltd (742235419)

Establishment

Name	Address	ID/FEI	Business Operations
Grahams Natural Alternatives Pty Ltd		742235419	manufacture(42387-135)

Revised: 8/2016

Grahams Natural Alternatives Pty Ltd