

**GN KIDS ECZEMA - oatmeal 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.*

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**DRUG FACTS**

**COLLOIDAL OATMEAL**

Keep Out Of Reach Of Children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Eczema Cream. For external use only.

Eczema cream, apply to affected area.

Topical cream. Apply as needed to affected areas.

For External use only. When using this product do not get into eyes.

If pregnant or breastfeeding, ask a professional before use.

Stop use and ask doctor if conditions worsen, symptoms last more than 7 days or clear up and occur again in a few days.

Water, Theobroma Oil, Olea Europaea Fruit Oil, Vitellaria Paradoxa, Simmondsia Chimensis Seed Oil, D-Alpha Tocopheryl Acetate, Vanilla Planifolia tincture, Allantoin, Sodium Benzoate, Potassium Sorbate, Cetyl Alcohol, Caprylic/Capric Triglyceride, Cetearyl Glucoside, Cetostearyl Alcohol, Bisabolol, Sclerotium Gum.





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 ■ PANTONE 123 C 
 ■ PANTONE 431 C

image of box

## GN KIDS ECZEMA

oatmeal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42387-123
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	25 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
COCOA BUTTER (UNII: 512OYT1CRR)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SHEANUT OIL (UNII: O88E196QRF)	
JOJOBA OIL (UNII: 724GKU717M)	

<b>.ALPHA.-TOCOPHEROL, D-</b> (UNII: N9PR3490H9)
<b>VANILLA</b> (UNII: Q74T35078H)
<b>ALLANTOIN</b> (UNII: 344S277G0Z)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128MIS)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>BETASIZOFIRAN</b> (UNII: 2X51AD1X3T)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42387-123-01	1 in 1 CARTON		
1	NDC:42387-123-00	73.7 g in 1 TUBE		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/24/2012	

**Labeler** - Grahams Natural Alternatives Pty Ltd (742235419)

**Registrant** - COSMETIC MANUFACTURERS (AUST) PTY. LTD. (758742308)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
COSMETIC MANUFACTURERS (AUST) PTY. LTD.		758742308	manufacture(42387-123)