#### 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.

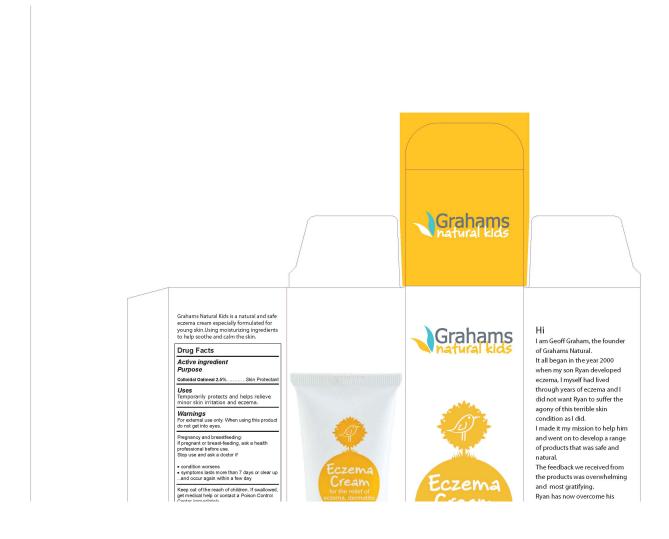
Topical cream. Apply as needed to affected areas.

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 7days 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, Capryllic/Capric Triglyceride, Cetearyl Glucoside, Cetostearyl Alcohol, Bisabolol, Sclerotium Gum.





## image of box

## **GN KIDS ECZEMA**

oatmeal cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42387-123	
Route of Administration	TOPICAL			

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

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCOA BUTTER (UNII: 5120 YT1CRR)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SHEANUT OIL (UNII: O88E196QRF)	
JOJOBA OIL (UNII: 724GKU717M)	

.ALPHATOCOPHEROL, D- (UNII: N9PR3490H9)	
VANILLA (UNII: Q74T35078H)	
ALLANTO IN (UNII: 344S277G0 Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETEARYL GLUCO SIDE (UNII: 09 FUA47KNA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LEVOMENOL (UNII: 24WE03BX2T)	
BETASIZO FIRAN (UNII: 2X51AD1X3T)	

P	ackaging			
#	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		

Marketing Information				
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)

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

Revised: 8/2012 Grahams Natural Alternatives Pty Ltd