ECZEMA CARE SKIN PROTECTANT- oatmeal lotion KAS Direct LLC dba BabyGanics

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.

eczema care skin protectant cream

Drug Facts

Active ingredient

Colloidal oatmeal 1%

Purpose

Skin protectant

Uses

temporarily protects and helps relieve minor skin irritation and itching due to:

- rashes
- eczema

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

- apply as needed
- massage into baby's skin, especially after bathing
- for use on mild to moderate eczema or as directed by a physician

Other information

store at room temperature 59-77°F (15-25°C)

Inactive ingredients

water, butyrospermum parkii (shea) butter¹, cetearyl alcohol, cetyl alcohol, isopropyl palmitate, glycerin¹, glyceryl stearate, theobroma cacao (cocoa) seed butter¹, hydrolyzed oats, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil¹, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil¹, rubus idaeus (red raspberry) seed oil,

cetearyl glucoside, tocopherol, glyceryl dilaurate, caprylyl glycol, xanthan gum, sodium hydroxide, sodium phytate, triethyl citrate, ethylhexylglycerin, benzoic acid.

1 Certified Organic Ingredient Unless otherwise specified, product not labeled as organic

dist. by KAS direct, LLC Westbury, NY 11590

PRINCIPAL DISPLAY PANEL - 226 g Tube Label

ACCEPTED NATIONALECZEMA.ORG NATIONAL ECZEMA ASSOCIATION

babyganics

eczema care skin protectant cream

fragrance free

relieves dry, itchy, irritated skin non-allergenic · pediatrician & dermatologist tested

formulated with: colloidal oatmeal*

formulated without: cortisone, steroids, parabens, phthalates or fragrances

Discover which of our ingredients are Certified Organic on back panel.

Net wt 8 OZ (226 g)

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†Certified Organic Ingredient Unless otherwise specified, product not labeled as organic *Learn more about these and all our ingredients and the choices we make at babyganics.com/13044





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1 800 378 7803









babyganics

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ECZEMA CARE SKIN PROTECTANT

oatmeal lotion

Product Information

NDC:59062-1305 HUMAN OTC DRUG Item Code (Source) Product Type

Route of Administration

TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)	OATMEAL	10 mg in 1 g			

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3M)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)		
COCOA BUTTER (UNII: 512OYT1CRR)		
OAT (UNII: Z6J799EAJK)		
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
RASPBERRY SEED OIL (UNII: 9S8867952A)		
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)		
CETEARYL GLUCO SIDE (UNII: 09 FUA 47 KNA)		
TOCOPHEROL (UNII: R0ZB2556P8)		
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)		
XANTHAN GUM (UNII: TTV12P4NEE)		
PHYTATE SO DIUM (UNII: 88496G1ERL)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
TOMATO (UNII: Z4KHF2C175)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
SO YBEAN OIL (UNII: 241ATL177A)		
Sodium Hydroxide (UNII: 55X04QC32I)		

l	Packaging						
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:59062-1305-8	226 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part347	04/08/2019			

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 7/2020

KAS Direct LLC dba BabyGanics