BABYGANICS ECZEMA- 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.

babyganics® Eczema Lotion

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 perfect for face and body
- 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) butter, cetearyl alcohol, cetyl alcohol, isopropyl palmitate, glycerin, glyceryl stearate, theobroma cacao (cocoa) seed butter, hydrolyzed oats, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil, rubus idaeus (red raspberry) seed oil,

cetearyl glucoside, tocopherol, glyceryl dilaurate, caprylyl glycol, xanthan gum, sodium phytate, ethylhexylglycerin, citric acid, sodium hydroxymethylglycinate

Dist. by: KAS Direct, LLC. Hicksville, NY 11801

PRINCIPAL DISPLAY PANEL - 226 g Tube Label

extra soothing

babyganics_®

eczema care skin protectant cream

with colloidal oatmeal · relieves dry, itchy, irritated skin · non–allergenic pediatrician & dermatologist tested

no: cortisone, steroids, parabens, sulfates, phthalates or fragrances

+ NeoNourish[®] Natural Seed Oil Blend

8 OZ (226g)

Drug Facts Active ingredient Purpose Colloidal oatmeal 1%. 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 - perfect for face and body · for use on mild to moderate eczema or as directed by Other information store at room temperature 59-77°F (15-25°C) Inactive ingredients water, butyrospermum parkii (shea) butter, cetearyl alcohol, cetyl alcohol, isopropyl palmitate, glycerin, glyceryl stearate, theobroma cacao (cocoa) seed butter, hydrolyzed oats, solanum lycopersicum (tomato) seed oil, helianthus annuus (sunflower) seed oil, vaccinium macrocarpon (cranberry) seed oil, nigella sativa (black cumin) seed oil, rubus idaeus (red raspberry) seed oil, sodium hydroxymethylglycinate, cetearyl glucoside, tocopherol, glyceryl dilaurate, caprylyl glycol,

NeoNourish* Natural Seed Oil Blend is designed to help nurture and support the unique needsof baby's skin. Natural tomato, sunflower, cranberry, black cumin and red raspberry seed oils help support healthy skin development and deliver antioxidant protection.

xanthan gum, sodium phytate, ethylhexylglycerin, citric acid



pediatrician + dermatologist tested



to learn more, please visit babyganics.com



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please recycle we do:) made in the USA never tested

on animals



eczema care skin protectant cream with colloidal oatmeal · relieves dry, itchy, irritated skin · non-allergenic pediatrician & dermatologist tested no: cortisone, steroids, parabens, sulfates, phthalates or fragrances + NeoNourish* Natural Seed Oil Blend 8 OZ (226g)

BABYGANICS ECZEMA

oatmeal lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59062-1304

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 3 M)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
COCOA BUTTER (UNII: 512OYT1CRR)	
OAT (UNII: Z6J799EAJK)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
CARROT SEED OIL (UNII: 595AO13F11)	
CHIA SEED OIL (UNII: MC2LH51BO7)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
CETEARYL GLUCO SIDE (UNII: 09 FUA47KNA)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHYTATE SO DIUM (UNII: 88496G1ERL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
SODIUM HYDRO XYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:59062-1304-1	226 g in 1 TUBE; Type 0: Not a Combination Product	06/21/2013		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part347	06/21/2013		