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.

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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 - 85 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

3 OZ (85g)

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pediatrician + dermatologist tested

to learn more, please visit **babyganics.com**

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1 800 378 7803
please recycle we do :)

made in the USA
never tested on animals

028-13037-01

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BABYGANICS ECZEMA

oatmeal lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59062-1303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
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 GLUCOSIDE (UNII: 09FUA47KNA)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1303-1	85 g in 1 TUBE		

Marketing Information

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

Labeler - KAS Direct LLC dba BabyGanics (002764605)

Revised: 4/2014 KAS Direct LLC dba BabyGanics