

BABYGANICS DIAPER RASH- zinc oxide cream

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® diaper rash cream

Drug Facts

Active ingredient

Zinc oxide 15%

Purpose

Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash
- helps seal out wetness

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

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

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

Inactive ingredients

water, butyrospermum parkii (shea) butter, theobroma cacao (cocoa) seed butter, prunus amygdalus dulcis (sweet almond) oil, glycol stearate, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3 polyricinoleate, glycerin, tocopheryl acetate, 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, calendula officinalis flower extract, aloe barbadensis leaf juice, sorbitan sesquioleate, cetyl ricinoleate, glyceryl caprate, beeswax, sodium polyacryloyldimethyl taurate, hydroxyethylcellulose, hydrogenated polydecene, trideceth-10, butylene glycol, magnesium stearate, aluminum tristearate, sodium benzoate, gluconolactone

Dist. by:

KAS Direct, LLC.

Hicksville, NY 11801

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

**treats &
protects**

babyganics®

diaper rash cream

with zinc oxide, calendula, aloe &
jojoba · helps prevent diaper rash
promotes healing · non allergenic
pediatrician & dermatologist tested

no: parabens, phthalates, petroleum,
mineral oil, dyes or fragrances

+ NeoNourish® Natural Seed Oil Blend

4 OZ (113g)



treats & protects

treats & protects

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



babyganics[®]

diaper rash cream

with zinc oxide, calendula, aloe & jojoba · helps prevent diaper rash
promotes healing · non allergenic
pediatrician & dermatologist tested

no: parabens, phthalates, petroleum,
mineral oil, dyes or fragrances

+ NeoNourish[®] Natural Seed Oil Blend

4 OZ (113g)

babyganics[®]

diaper rash cream

with zinc oxide, calendula, aloe & jojoba · helps prevent diaper rash
promotes healing · non allergenic
pediatrician & dermatologist tested



dermatologist tested



to learn more,
please visit
babyganics.com



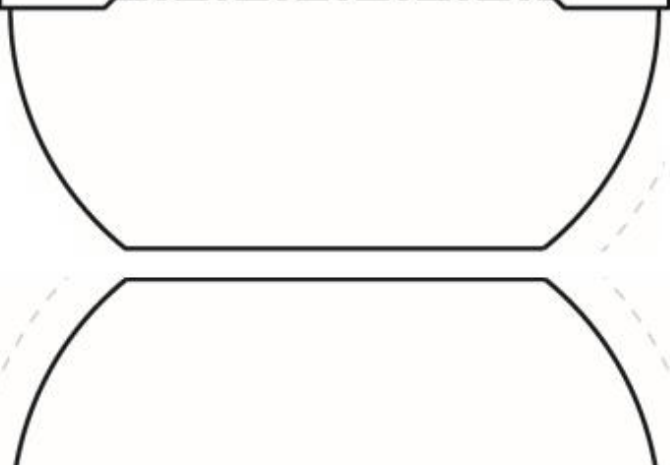
© 2014 dist. by
KAS Direct, LLC
Westbury, NY 11590



1 800 378 7803
please recycle
we do :)



made in the USA
never tested
on animals



babyyganics
 diaper rash cream

with zinc oxide, calendula, aloe & jojoba · helps prevent diaper rash
 promotes healing · non allergenic
 pediatrician & dermatologist tested



babyyganics®

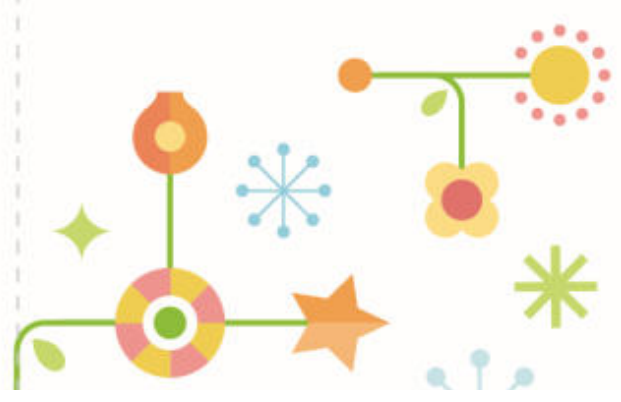
diaper rash cream

with zinc oxide, calendula, aloe & jojoba
 helps prevent diaper rash · promotes healing
 non allergenic · pediatrician & dermatologist tested

no: parabens, phthalates, petroleum,
 mineral oil, dyes or fragrances

+ NeoNourish® Natural Seed Oil Blend

4 OZ (113g)



Drug Facts

Active ingredients	Purpose
Zinc oxide 15%	Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash
- helps seal out wetness

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

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information store at room temperature



temperature 59-77° (15-25°C)

Inactive ingredients water, butyrospermum parkii (shea) butter, theobroma cacao (cocoa) seed butter, prunus amygdalus dulcis (sweet almond) oil, glycol stearate, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3 polyricinoleate, glycerin, tocopheryl acetate, 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, calendula officinalis flower extract, aloe barbadensis leaf juice, sorbitan sesquioleate, cetyl ricinoleate, glyceryl caprate, beeswax, sodium polyacryloyldimethyl taurate, hydroxyethylcellulose, hydrogenated polydecene, trideceth-10, butylene glycol, magnesium stearate, aluminum tristearate, sodium benzoate, gluconolactone

BABYGANICS DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59062-1219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEANUT OIL (UNII: O88E196QRF)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
CETYL RICINOLEATE (UNII: 1P677500YD)	
GLYCERYL CAPRATE (UNII: 197M6VFC1W)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SODIUM TAURATE (UNII: Y7LJA74T0N)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIDECETH-10 (UNII: G624N6MSBA)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59062-1219-1	1 in 1 CARTON	06/21/2013	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

