

AVEENO BABY ECZEMA THERAPY NIGHTTIME BALM- oatmeal cream
Johnson & Johnson Consumer Inc.

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.

Aveeno Baby® Eczema Therapy NIGHTTIME BALM

Drug Facts

Active Ingredient

Colloidal Oatmeal 1%

Purpose

Skin protectant

Uses

- Temporarily protects and helps relieve minor skin irritation and itching due to:
 - eczema
 - rashes

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.

Other Information

- Do not use if quality seal is broken or missing.
- Protect from Excessive Heat (40°C/104°F).

Inactive Ingredients

Glycerin, Water, Cetearyl Alcohol, Isocetyl Alcohol, Dimethicone, Cetyl Alcohol, Ethylhexylglycerin, *Avena Sativa* (Oat) Kernel Oil, *Avena Sativa* (Oat) Kernel Extract, Ceramide NP, Caprylic/Capric Triglyceride, Sodium Cetearyl Sulfate, Potassium Phosphate, Dipotassium Phosphate, Stearic Acid, Sodium Hydroxide, Citric Acid, Benzyl Alcohol, p-Anisic Acid, Benzoic Acid.

Questions or Comments?

Call toll-free **866-4AVEENO (866-428-3366)** or **215-273-8755** (collect)

www.aveeno.com

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 312 g Jar Label

**Aveeno
Baby®**

**Eczema
Therapy**

NIGHTTIME BALM

colloidal oatmeal . skin protectant cream

Steroid-free . Fragrance-free . Paraben-free .

Phthalate-free . Hypoallergenic

**Specially formulated to provide immediate
and long-lasting moisture through the night.**

ACCEPTED

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NATIONALECZEMA.ORG

NATIONAL

ECZEMA

ASSOCIATION

PEDIATRICIAN

RECOMMENDED

BRAND

NET WT. 11 OZ (312g)

Aveeno Baby

Eczema Therapy

NIGHTTIME BALM

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PEDIATRICIAN
RECOMMENDED
BRAND

Only AVEENO® has harnessed the soothing power of ACTIVE NATURALS® oatmeal to create a nighttime balm that helps care for your baby's skin with eczema. This unique balm intensely moisturizes without leaving a greasy feeling behind. It helps strengthen the skin's natural moisture barrier and helps prevent recurrence of dry, itchy skin from eczema. And soothes dry, itchy skin, so your baby will feel relief when applied at bedtime. Gentle enough for everyday use on babies' sensitive skin. Steroid-free, Fragrance-free, Paraben-free, Hypoallergenic.

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Skillman, NJ 08558 QJ&JCI 2017 30037140



Drug Facts		Drug Facts (cont.)
Active ingredient Colloidal Oatmeal 1%	Purpose Skin Protectant	Other information • Do not use if quality seal is broken or missing. • Protect from Excessive Heat (40°C/104°F).
Uses • Temporarily protects and helps relieve minor skin irritation and itching due to: • eczema • rashes		Inactive ingredients Glycerin, Water, Cetearyl Alcohol, Isocetyl Alcohol, Dimethicone, Cetyl Alcohol, Benzyl Alcohol, Ethylhexylglycerin, Sodium Cetearyl Sulfate, Benzoic Acid, Stearic Acid, Dipotassium Phosphate, Potassium Phosphate, p-Anisic Acid, Caprylic/Capric Triglyceride, Sodium Hydroxide, Avena Sativa (Oat) Kernel Oil, Ceramide NP, Citric Acid, Avena Sativa (Oat) Kernel Extract
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.		Questions or comments? Call toll-free 866-4-AVEENO (866-428-3366) or 215-273-8755 (collect) www.aveeno.com
Directions • Apply as needed.		

AVEENO BABY ECZEMA THERAPY NIGHTTIME BALM

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0369
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)	
Glycerin (UNII: PDC6A3C0OX)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	

Isocetyl Alcohol (UNII: 1800H64066)
Dimethicone (UNII: 92RU3N3Y1O)
Cetyl Alcohol (UNII: 936JST6JCN)
Ethylhexylglycerin (UNII: 147D247K3P)
Oat Kernel Oil (UNII: 3UVP41R77R)
Oat (UNII: Z6J799EAJK)
Ceramide NP (UNII: 4370DF050B)
Medium-Chain Triglycerides (UNII: C9H2L21V7U)
Sodium Cetostearyl Sulfate (UNII: 7ZBS06BH4B)
Potassium Phosphate, Unspecified Form (UNII: B7862WZ632)
Dibasic Potassium Phosphate (UNII: CI71S98N1Z)
Stearic Acid (UNII: 4ELV7Z65AP)
Sodium Hydroxide (UNII: 55X04QC32I)
Benzyl Alcohol (UNII: LKG8494WBH)
p-Anisic Acid (UNII: 4SB6Y7DMM3)
Benzoic Acid (UNII: 8SKN0B0MIM)
Citric Acid Monohydrate (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0369-1	28 g in 1 JAR; Type 0: Not a Combination Product	12/01/2017	02/11/2021
2	NDC:69968-0369-2	312 g in 1 JAR; Type 0: Not a Combination Product	12/01/2017	01/21/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	12/01/2017	02/11/2021

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 4/2019

Johnson & Johnson Consumer Inc.