

**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**

**new**

**Aveeno  
Baby®**

**Eczema  
Therapy**

**NIGHTTIME BALM  
colloidal oatmeal . skin protectant cream**

**Paraben-free . Steroid-free . Fragrance-free  
Relieves dry, itchy, irritated skin due to eczema**

**ACCEPTED**

**e  
NATIONALECZEMA.ORG**

**NATIONAL  
ECZEMA  
ASSOCIATION**

**PEDIATRICIAN  
RECOMMENDED  
BRAND**

**NET WT. 11 OZ (312g)**

**Aveeno**<sup>new</sup>  
Baby

**Eczema  
Therapy**

**NIGHTTIME BALM**

colloidal oatmeal • skin protectant cream

Paraben-free • Steroid-free • Fragrance-free  
Relieves dry, itchy, irritated skin due to eczema

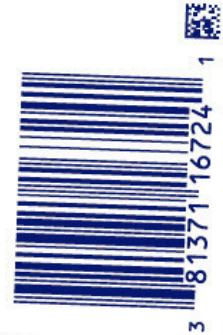


**PEDIATRICIAN  
RECOMMENDED  
BRAND**

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. As part of a bedtime routine, also try AVEENO® Baby Cleansing Therapy Moisturizing Wash for gentle cleansing.

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
Skillman, NJ 08558 ©J&JCI 2016 30032931

**NET WT. 11 OZ (312g)**



|   |                                   |  |  |
|---|-----------------------------------|--|--|
| <b>Drug Facts</b>   |                                   | <b>Drug Facts (cont.)</b>  |  |
| <b>Active Ingredient</b><br>Colloidal Oatmeal 1%  | <b>Purpose</b><br>Skin Protectant | <b>Other Information</b> • Do not use if quality seal is broken or missing.<br>• Protect from Excessive Heat (40°C/104°F).   |  |
| <b>Uses</b> • Temporarily protects and helps relieve minor skin irritation and itching due to: • eczema • rashes  |                                   | <b>Inactive Ingredients:</b> 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. |  |
| <b>Warnings</b><br><b>For external use only.</b><br><b>When using this product</b><br>• do not get into eyes.<br><b>Stop use and ask a doctor if:</b><br>• condition worsens • symptoms last more than 7 days or clear up and occur again within a few days.<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. |                                   | <b>Questions or comments?</b> Call toll-free 866-4-AVEENO (866-426-3366) or 215-273-8755 (collect) <a href="http://www.aveeno.com">www.aveeno.com</a>  |  |
| <b>Directions</b> • Apply as needed.  |                                   |  |  |

## AVEENO BABY ECZEMA THERAPY NIGHTTIME BALM

oatmeal cream

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69968-0020 |
| <b>Route of Administration</b> | 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) |          |

|   |
|---|
| <b>Glycerin</b> (UNII: PDC6A3C0OX)                              |
| <b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)                   |
| <b>Isocetyl Alcohol</b> (UNII: 1800H64066)                      |
| <b>Dimethicone</b> (UNII: 92RU3N3Y1O)                           |
| <b>Cetyl Alcohol</b> (UNII: 936JST6JCN)                         |
| <b>Ethylhexylglycerin</b> (UNII: 147D247K3P)                    |
| <b>Oat Kernel Oil</b> (UNII: 3UVP41R77R)                        |
| <b>Oat</b> (UNII: Z6J799EAJK)                                   |
| <b>Ceramide NP</b> (UNII: 4370DF050B)                           |
| <b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)            |
| <b>Sodium Cetostearyl Sulfate</b> (UNII: 7ZBS06BH4B)            |
| <b>Potassium Phosphate, Unspecified Form</b> (UNII: B7862WZ632) |
| <b>Potassium Phosphate, Dibasic</b> (UNII: CI71S98N1Z)          |
| <b>Stearic Acid</b> (UNII: 4ELV7Z65AP)                          |
| <b>Sodium Hydroxide</b> (UNII: 55X04QC32I)                      |
| <b>Benzyl Alcohol</b> (UNII: LKG8494WBH)                        |
| <b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)                          |
| <b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)               |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69968-0020-1 | 28 g in 1 JAR; Type 0: Not a Combination Product  | 06/01/2016           |                    |
| 2 | NDC:69968-0020-2 | 312 g in 1 JAR; Type 0: Not a Combination Product | 06/01/2016           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part347                                  | 06/01/2016           |                    |

**Labeler** - Johnson & Johnson Consumer Inc. (002347102)

Revised: 7/2016

Johnson & Johnson Consumer Inc.