

**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, 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

Questions?

866-428-3366; Outside US, dial collect **215-273-8755** www.aveeno.com

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 312 g Jar Label

Aveeno[®]

baby

NEW

LOOK

Same

Great

Formula

eczema

therapy

nighttime balm

colloidal oatmeal skin

protectant + ceramide

NET WT. 11 OZ (312 g)

Recommended

by Pediatricians &

Dermatologists

clinically proven to

relieve itchy, dry,

irritated skin due

to eczema

fragrance-free

hypoallergenic

steroid-free

ACCEPTED

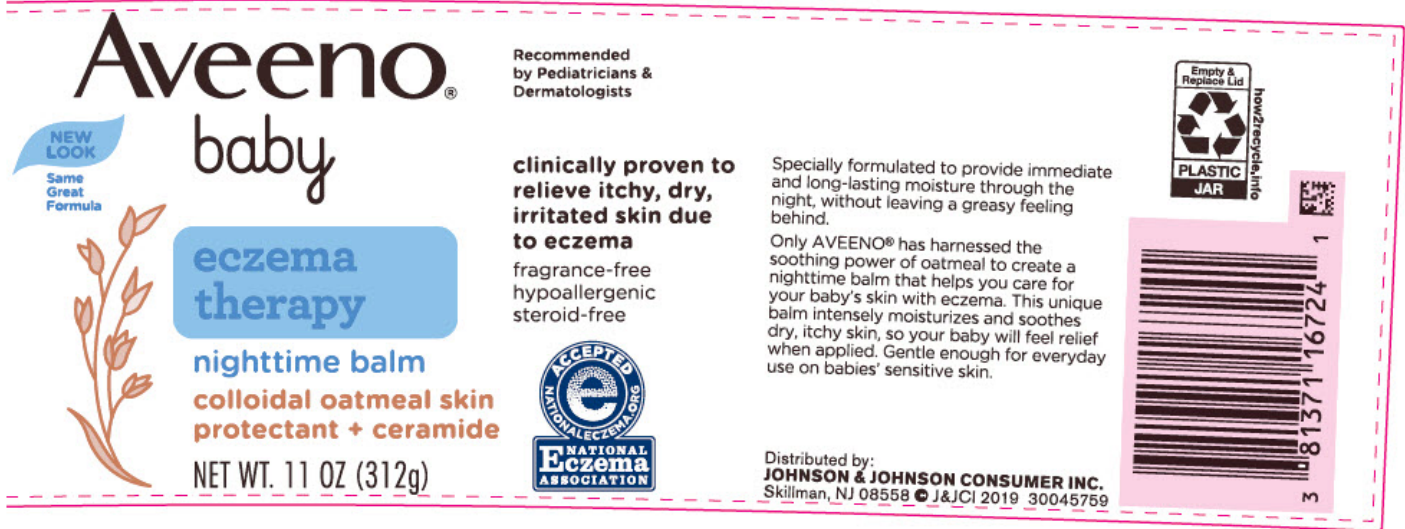
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ASSOCIATION



Aveeno[®]
baby
eczema therapy
nighttime balm
colloidal oatmeal skin protectant + ceramide
NET WT. 11 OZ (312g)

Recommended by Pediatricians & Dermatologists

clinically proven to relieve itchy, dry, irritated skin due to eczema
fragrance-free
hypoallergenic
steroid-free

Specially formulated to provide immediate and long-lasting moisture through the night, without leaving a greasy feeling behind.
Only AVEENO[®] has harnessed the soothing power of oatmeal to create a nighttime balm that helps you care for your baby's skin with eczema. This unique balm intensely moisturizes and soothes dry, itchy skin, so your baby will feel relief when applied. Gentle enough for everyday use on babies' sensitive skin.

Empty & Replace Lid
PLASTIC JAR
how2recycle.com

81371 16724 1

Accepted National Eczema Association

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free of parabens, phthalates, phenoxyethanol

Drug Facts		Drug Facts (continued)	
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? 866-428-3366; Outside US, dial collect 215-273-8755 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:69968-0540
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOCETYL ALCOHOL (UNII: 1800H64066)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
P-ANISIC ACID (UNII: 4SB6Y7DMM3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
CERAMIDE NP (UNII: 4370DF050B)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OAT (UNII: Z6J799EAJK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0540-2	28 g in 1 JAR; Type 0: Not a Combination Product	03/25/2019	
2	NDC:69968-0540-5	156 g in 1 JAR; Type 0: Not a Combination Product	03/25/2019	
3	NDC:69968-0540-1	312 g in 1 JAR; Type 0: Not a Combination Product	03/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/25/2019	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

