AVEENO BABY ECZEMA THERAPY MOISTURIZING- 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 moisturizing cream

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

- To open, twist off cap and remove quality seal.
- Do not use if quality seal is broken.

- For use on mild to moderate eczema or as directed by a physician.
- Store at room temperature.

Inactive ingredients

Water, Glycerin, Panthenol, Distearyldimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Dimethicone, Avena Sativa (Oat) Kernel Oil, Steareth-20, Benzalkonium Chloride, Ceramide NP, Sodium Chloride, 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 - 206 g Tube Label

RECOMMENDED BY PEDIATRICIANS & DERMATOLOGISTS

Aveeno ®

baby

NEW

LOOK

Same Great

Formula

eczema

therapy

moisturizing cream

colloidal oatmeal

skin protectant

+ vitamin B 5

clinically proven to

relieve itchy, irritated

skin due to eczema

ACCEPTED

e

NATIONALECZEMA.ORG

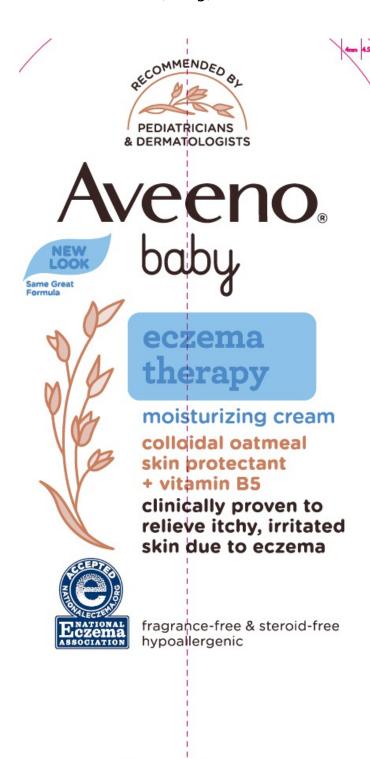
NATIONAL

ECZEMA

ASSOCIATION

fragrance-free & steroid-free,

NET WT. 7.3 OZ. (206g)



NET WT. 7.3 OZ (206 g)



Care for your baby's eczema-prone skin with the soothing power of natural colloidal oatmeal. This breakthrough cream intensely moisturizes and helps prevent the recurrence of extra dry skin from eczema.

pH-balanced • non-greasy free of parabens, phthalates, phenoxyethanol, steroids

AVEENO® is a Pediatrician and Dermatologist recommended brand

Drug Facts	
Active ingredient	Purpose
Colloidal Oatmeal 1%	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 • To open, twist off cap and remove quality seal. • Do not use if quality seal is broken. • For use on mild to moderate eczema or as directed by a physician. • Store at room temperature.

Inactive ingredients Water, Glycerin, Panthenol, Distearyldimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Dimethicone, Avena Sativa (Oat) Kernel Oil, Steareth-20, Benzalkonium Chloride, Ceramide NP, Sodium Chloride, Avena Sativa (Oat) Kernel Extract

Questions? 866-428-3366; Qutside US, dial collect 215-273-8755 www.aveeno.com |

Distributed by: JOHNSON & JOHNSON CONSUMER INC. Skillman, NJ 08558 ©J&JCI 2020 30045764





AVEENO BABY ECZEMA THERAPY MOISTURIZING

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0404
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)		
PANTHENOL (UNII: WW9CM0O67Z)		
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)		
PETROLATUM (UNII: 4T6H12BN9U)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
OAT KERNEL OIL (UNII: 3UVP41R77R)		
STEARETH-20 (UNII: LOQ8IK9E08)		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
CERAMIDE NP (UNII: 4370DF050B)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
OAT (UNII: Z 6J799EAJK)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69968- 0404-5	141 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2010		
2	NDC:69968- 0404-7	206 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2010		
3	NDC:69968- 0404-1	14 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2010		
4	NDC:69968- 0404-2	354 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2013	11/30/2020	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/01/2010	

Labeler - Johnson & Johnson Consumer Inc. (118772437)