

**AVEENO® BABY CALMING COMFORT BATH PLUS SET- dimethicone
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 calming comfort® bath plus lotion set

Aveeno baby calming comfort® lotion

Drug Facts

Active ingredient

Dimethicone 1.2%

Purpose

Skin protectant

Uses

- Temporarily protects and helps relieve chafed, chapped, or cracked skin
- Helps prevent and protect from the drying effects of wind and cold weather.

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.

Do not use on

- Deep or puncture wounds
- Animal bites
- Serious burns

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 seal is broken.
- Store at room temperature.

Inactive ingredients

Water , Glycerin, Distearyltrimonium Chloride ,Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Fragrance, Sodium Chloride

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 - Kit Packet

Aveeno®

baby

calming comfort®

bath + lotion set

18 FL OZ (532 mL)

NET WT. 8 OZ (227 g)

baby
Aveeno®

Aveeno®
baby

We use high quality, natural oats, and carefully harvest their moisturizing and soothing properties.

calming comfort® bath

Gently cleanses baby's skin and leaves skin feeling soft & healthy. Helps calm baby before bedtime.

 **natural oat extract**
carefully extracted from the oat kernel

 **lavender scent**
known for its calming properties

pH-balanced • tear-free

free of sulfates, soap, parabens, phthalates, phenoxyethanol

Directions Dispense directly into bath water. Or dispense onto a wet washcloth or hand and apply to hair and body. Lather and rinse.


SAFETY WARNING Keep this product out of reach of children. Do not use if quality seal is broken or missing. Do not use without consulting a doctor if child has asthma or allergies or if there is a family history of either. Serious breathing problems could occur.

Ingredients Water, Cocamidopropyl Betaine, Sodium Lauroamphoacetate, Glycerin, Coco-Glucoside, Sodium Chloride, Hydroxypropyl Starch Phosphate, Citric Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Sodium Benzoate, Glyceryl Oleate, Polyquaternium-7, Sodium Hydroxide, Avena Sativa (Oat) Kernel Extract

calming comfort® lotion

Moisturizes baby's skin for 24hrs and leaves skin soft, smooth and healthy-looking. Helps calm baby before bedtime.

 **natural oatmeal**
finely-milled and locks in moisture

 **lavender scent**
known for its calming properties

pH-balanced • non-greasy

free of parabens, phthalates, phenoxyethanol, steroids

AVEENO® is a Pediatrician and Dermatologist recommended brand

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AVEENO BABY CALMING COMFORT BATH PLUS SET

dimethicone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0631
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0631-9	1 in 1 PACKET	08/03/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	227 g
Part 2	1 BOTTLE	532 mL

Part 1 of 2

AVEENO BABY CALMING COMFORT

dimethicone lotion

Product Information

Item Code (Source) NDC:69968-0656

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	12 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0656-8	227 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	06/01/2020	

Part 2 of 2

AVEENO BABY CALMING COMFORT BATH

other baby products solution

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	COCO GLUCOSIDE (UNII: ICS790225B)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	GLYCERYL OLEATE (UNII: 4PC054V79P)	
INGR	POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	OAT (UNII: Z6J799EAJK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		532 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/03/2020	

Labeler - Johnson & Johnson Consumer Inc. (118772437)