

AVEENO BABY BATHTIME SOLUTIONS BABY AND MOMMY GIFT 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® Daily Moisture Lotion

Drug Facts

Active ingredient

Dimethicone 1.2%

Purpose

Skin Protectant

Uses

- Helps prevent and temporarily protects chafed, chapped or cracked skin

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

- Remove quality seal. Do not use if quality 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, Sodium Chloride, Allantoin

Questions?

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

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CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - Kit Container

Aveeno

Baby®

bathtime solutions

baby & mommy gift set

FOR BABY

Wash & Shampoo, 8 fl oz (236 mL)

Daily Moisture Lotion, 8 oz (227 g)

CALMING COMFORT® Bath, 8 fl oz (236 mL)

FOR MOMMY

Stress Relief Body Wash, 12 fl oz (354 mL)

Free Reusable Canvas Box

PEDIATRICIAN

Aveeno®

RECOMMENDED®

Naturally Nourishing Solutions for Precious Bathtime Moments



Aveeno

Baby[®]

bathtime solutions

baby & mommy gift set

FOR BABY

Wash & Shampoo, 8 fl oz (236 mL)
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Stress Relief Body Wash, 12 fl oz (354 mL)
Free Reusable Canvas Box

Naturally Nourishing Solutions for Precious Bathtime Moments

AVEENO[®] Baby Wash & Shampoo 8 fl oz (236 mL)

- Tear-Free
- Gentle Cleansing for Hair & Body

DIRECTIONS Twist off cap, remove quality seal. Do not use if seal is broken. Pour onto a wet washcloth or hand and apply to hair and body. Or pour directly into bath water. Lather and rinse.

Safety Tip Keep this product out of reach of children.

Ingredients Water, Cocamidopropyl Betaine, Glycerin, Sodium Lauroamphoacetate, Coco-Glucoside, Sodium Chloride, Citric Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Benzoate, Glyceryl Oleate, Sodium Hydroxide, Fragrance, Polyquaternium-10, Guar Hydroxypropyltrimonium Chloride, Butylene Glycol, Avena Sativa (Oat) Kernel Extract
Made in Canada

AVEENO[®] Baby Daily Moisture Lotion 8 oz (227 g)

Drug Facts	
Active ingredient	Purpose
Dimethicone 1.2%	Skin protectant
Uses • Helps prevent and temporarily protects chafed, chapped, or cracked skin.	
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 quality 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, Sodium Chloride, Allantoin	

Discover
Nature's Secret
for Baby's
Healthy Skin

AVEENO[®] Baby CALMING COMFORT[®] Bath 8 fl oz (236 mL)

Directions Shake well. Before first use, twist off cap and remove quality seal. Do not use if seal is broken. Dispense onto a wet washcloth or hand and apply to body. Or pour desired amount under running water, swirl to mix. Lather and rinse.

Safety Warning Keep this product out of reach of children. 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, Glycerin, Sodium Lauroamphoacetate, Coco-Glucoside, Sodium Chloride, Hydroxypropyl Starch Phosphate, Citric Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Sodium Benzoate, Glyceryl Oleate, Polyquaternium-7, Sodium Hydroxide, Butylene Glycol, Avena Sativa (Oat) Kernel Extract
Made in Canada

AVEENO[®] Stress Relief Body Wash 12 fl oz (354 mL)

For Daily Use Shake well before use. Squeeze body wash onto wet pouf, washcloth or hands. Work into a rich creamy lather, then rinse.

For Shaving Apply by hand as a rich shaving lotion for silky, smooth legs.

Ingredients Water, Glycerin, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Avena Sativa (Oat) Kernel Flour, Guar Hydroxypropyltrimonium Chloride, Fragrance, Tetrasodium EDTA, Glycol Distearate, Polyquaternium-10, Quaternium-15, Citric Acid, Myristyl Alcohol, Hydroxypropyltrimonium Hydrolyzed Wheat Protein, Hydroxypropyltrimonium Hydrolyzed Wheat Starch
Made in Canada

Canvas Box: Made in China

SAFETY TIP: This is not a toy. Keep out of reach of children. Discard all packaging materials immediately after opening.

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



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The AVEENO® Baby Bathtime Solutions Gift Set includes key products for helping to take care of your new baby's skin with a special bonus for you! These AVEENO® Baby products contain oat and are formulated to naturally nourish your baby's skin.

These AVEENO® Baby products are paraben-free and phthalate-free.

YOUR GIFT SET INCLUDES:

AVEENO® Baby Wash & Shampoo – This tear-free, soap-free, hypoallergenic wash and shampoo cleanses your baby's skin without drying. Gentle enough to use every day, your baby will be squeaky clean and ready for playtime, bedtime and everything in between.

AVEENO® Baby Daily Moisture Lotion – This nourishing moisturizer soothes and helps relieve your baby's delicate, dry skin. Clinically proven to moisturize for 24 hours, this hypoallergenic and fragrance-free lotion can be used daily to help keep baby's sensitive skin soft, smooth and healthy-looking.

AVEENO® Baby CALMING COMFORT® Bath – This tear-free, soap-free, hypoallergenic cleanser contains scents of lavender and vanilla to help calm baby before bedtime. Combine with a warm bath to naturally relax your baby so that she can sleep more restfully.

AVEENO® Stress Relief Body Wash – This unique formula, which combines skin-soothing oat with scents of lavender, chamomile and ylang-ylang oils, helps moisturize

AVEENO BABY BATHTIME SOLUTIONS BABY AND MOMMY GIFT SET

dimethicone kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0593

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0593-1	1 in 1 CONTAINER	06/16/2019	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	227 mL
Part 2	1 BOTTLE	236 mL
Part 3	1 BOTTLE	236 mL
Part 4	1 BOTTLE	354 mL

Part 1 of 4

AVEENO BABY DAILY MOISTURE

dimethicone lotion

Product Information	
Item Code (Source)	NDC:69968-0441
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 mL
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Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Distearyldimonium Chloride (UNII: OM9573ZX3X)	
Petrolatum (UNII: 4T6HI2BN9U)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Cetyl Alcohol (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sodium Chloride (UNII: 451W47IQ8X)	
Allantoin (UNII: 344S277G0Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0441-8	227 mL 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	08/01/2001	

Part 2 of 4

AVEENO BABY WASH AND SHAMPOO

baby shampoos solution

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	Sodium Lauroamphoacetate (UNII: SLK428451L)	
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	Sodium Hydroxide (UNII: 55X04QC32I)			
INGR	Guar Hydroxypropyltrimonium Chloride (1.7 Substituents Per Saccharide) (UNII: B16G315W7A)			
INGR	Butylene Glycol (UNII: 3XUS85K0RA)			
INGR	OATMEAL (UNII: 8PI54V663Y)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236 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			06/01/2010	
Part 3 of 4				
AVEENO BABY CALMING COMFORT BATH				
baby shampoos solution				
Product Information				
Route of Administration		TOPICAL		
Other Ingredients				
Ingredient Kind		Ingredient Name	Quantity	
INGR		Water (UNII: 059QF0KO0R)		
INGR		Cocamidopropyl Betaine (UNII: 5OCF3O11KX)		
INGR		Glycerin (UNII: PDC6A3C0OX)		
INGR		Sodium Lauroamphoacetate (UNII: SLK428451L)		
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		Butylene Glycol (UNII: 3XUS85K0RA)		
INGR		OATMEAL (UNII: 8PI54V663Y)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236 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		06/01/2010	

Part 4 of 4	
AVEENO STRESS RELIEF BODY WASH	
bath soaps and detergents lotion	

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	OATMEAL (UNII: 8PI54V663Y)	
INGR	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
INGR	EDETATE SODIUM (UNII: MP1J8420LU)	
INGR	Glycol Distearate (UNII: 13W7MDN21W)	
INGR	Quaternium-15 (UNII: E40U03LEM0)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	Myristyl Alcohol (UNII: V42034O9PU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		354 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		06/01/2008	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/16/2019	

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 5/2019

Johnson & Johnson Consumer Inc.