

**AVEENO BABY CALMING COMFORT- dimethicone lotion**  
**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.*

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**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**

- Store at room temperature.
- Remove quality seal. Do not use if quality seal is broken.

## **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** visit [www.aveeno.com](http://www.aveeno.com)

Distributed by:

**JOHNSON & JOHNSON  
CONSUMER INC.**

Skillman, NJ 08558

## **PRINCIPAL DISPLAY PANEL - 532 mL Bottle Label**

RECOMMENDED BY  
PEDIATRICIANS  
& DERMATOLOGIST

**Aveeno**®

**New  
Look**

**baby**

New Gentle

Fragrance

**calming comfort**®

**lotion**

**natural oatmeal**

**+ lavender scent**

dimethicone skin protectant

**moisturizes baby's**

**skin for 24hrs**

**helps calm baby**

**before bedtime**

lavender &

vanilla scented

18 FL OZ (532 mL)

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lotion

**natural oatmeal  
+ lavender scent**  
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**moisturizes baby's  
skin for 24hrs**  
**helps calm baby  
before bedtime**

lavender & vanilla scented

18 FL OZ (532 mL)  
30045959

NEW LOOK  
New Gentle  
Fragrance

**calming comfort<sup>®</sup>**  
We use high quality, natural  
oats, and carefully harvest their  
protective, moisturizing and  
soothing properties.

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

**lavender scent**  
known for its calming properties

fast-absorbing formula clinically proven  
to moisturize for 24 hours

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

AVEENO<sup>®</sup> is a Pediatrician and Dermatologist recommended brand

<b>Drug Facts</b> <b>Active ingredient ..... Purpose</b> Dimethicone 1.2% .....Skin protectant	<b>Drug Facts</b> (continued) contact a Poison Control Center right away.
<b>Uses</b> • Temporarily protects and helps relieve chafed, chapped, or cracked skin, • Helps prevent and protect from the drying effects of wind and cold weather.	<b>Directions</b> • Apply as needed.
<b>Warnings</b> <b>For external use only.</b> <b>When using this product</b> • Do not get into eyes. <b>Stop use and ask a doctor if</b> • Condition worsens • Symptoms last more than 7 days or clear up and occur again within a few days. <b>Do not use on</b> • Deep or puncture wounds • Animal bites • Serious burns <b>Keep out of reach of children. If swallowed, get medical help or</b>	<b>Other information</b> • Store at room temperature. • Remove quality seal. Do not use if quality seal is broken. <b>Inactive ingredients</b> Water, Glycerin, Distearoyldimonium Chloride, Petrolatum, Isopropyl Palmitate, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Fragrance, Sodium Chloride
Distributed by: <b>JOHNSON &amp; JOHNSON CONSUMER INC.</b> Skillman, NJ 08558 ©J&JCI 2020 Made in Canada 30045966	<b>Questions?</b> 866-428-3366; Outside US, dial collect 215-273-8755 www.aveeno.com

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## AVEENO BABY CALMING COMFORT

dimethicone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69968-0629
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0629-1	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	
2	NDC:69968-0629-8	227 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2020	06/02/2020

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/01/2020	

**Labeler** - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023

Johnson & Johnson Consumer Inc.