

**AVEENO CRACKED SKIN RELIEF CICA BALM- dimethicone emulsion**  
**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 Skin Relief Cracked Skin Balm**

**Drug Facts**

**Active Ingredient**

Dimethicone (5%)

**Purpose**

Skin Protectant

**Use**

- Helps prevent and temporarily protects 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

**Inactive Ingredients**

Glycerin, Water, Cetearyl Alcohol, Isocetyl Alcohol, Cetyl Alcohol, Avena Sativa (Oat) Kernel Flour, Benzyl Alcohol, Ethylhexylglycerin, Sodium Cetearyl Sulfate, Benzoic Acid, Stearic Acid, Dipotassium Phosphate, Potassium Phosphate, Caprylic/Capric Triglyceride, p-Anisic Acid, Sodium Hydroxide, Avena Sativa (Oat) Kernel Oil, Citric Acid, Avena Sativa (Oat) Kernel Extract

## **Other Information**

Store at room temperature.

## **Questions?**

call toll-free **866-428-3366** or **215-273-8755 (collect)**. [www.aveeno.com](http://www.aveeno.com)

Distributed by:

**JOHNSON & JOHNSON**

**CONSUMER INC.**

Skillman, NJ 08558

## **PRINCIPAL DISPLAY PANEL - 312 g Jar Label**

**NEW**

**Aveeno®**

**CRACKED**

**SKIN RELIEF**

**CICA balm**

Dimethicone Skin Protectant

**Helps Relieve**

**Cracked Skin**

Intensely moisturizes on contact

**fragrance free**

**with**

**TRIPLE OAT COMPLEX**

**net wt. 11 oz (312g)**

**DERMATOLOGIST**

**THERAPEUTIC**

**RECOMMENDED BRAND**

**NEW**  
**Aveeno**<sup>®</sup>

**CRACKED  
SKIN RELIEF  
CICA balm**

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net wt. 11 oz (312 g)

**DERMATOLOGIST  
THERAPEUTIC  
RECOMMENDED BRAND**

Aveeno<sup>®</sup> Cracked Skin Relief CICA Balm helps protect & relieve chapped or cracked skin. Leaves skin feeling moisturized all day.

What is CICA?  
CICA comes from the French word "Cicatrisation" Aveeno<sup>®</sup> CICA balm is formulated to intensely moisturize & help repair dry skin.

Triple Oat Complex:  
Oat Flour, Oat Extract, Oat Oil

- Gentle on Sensitive Skin
- Hypoallergenic
- Paraben Free
- Steroid Free
- Fragrance Free

**Drug Facts**

Active ingredient	Purpose
Dimethicone 5% .....	Skin Protectant

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• Helps prevent and protect from the drying effects of wind and cold weather

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**Drug Facts (continued)**

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**Other information**

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**AVEENO CRACKED SKIN RELIEF CICA BALM**

dimethicone emulsion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69968-0350
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
Isocetyl Alcohol (UNII: 1800H64066)	
Benzoic acid (UNII: 8SKN0B0MIM)	
Cetyl Alcohol (UNII: 936JST6JCN)	
OATMEAL (UNII: 8PI54V663Y)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Ethylhexylglycerin (UNII: 147D247K3P)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
Stearic acid (UNII: 4ELV7Z65AP)	
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
p-Anisic Acid (UNII: 4SB6Y7DMM3)	
Sodium Hydroxide (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OAT (UNII: Z6J799EAJK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0350-1	28 g in 1 JAR; Type 0: Not a Combination Product	09/01/2018	
2	NDC:69968-0350-2	312 g in 1 JAR; Type 0: Not a Combination Product	09/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2018	

**Labeler** - Johnson & Johnson Consumer Inc. (002347102)

Revised: 12/2019

Johnson & Johnson Consumer Inc.