

**CETAPHIL SOOTHING GEL CREAM- allantoin cream**  
**Galderma Laboratories, L.P.**

*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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**Drug Facts**

**Active ingredients.....Purpose**

Allantoin 0.5%.....Skin Protectant

**Uses**

Temporarily protects minor: ●cuts  
●scrapes ●burns ■helps prevent and temporarily  
protects and helps relieve 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

**Inactive Ingredients**

ALOE BARBADENSIS LEAF JUICE POWDER, BUTYROSPERMUM PARKII (SHEA) OIL, CAPRYLYL GLYCOL, CAPRYLYL/CAPRYL GLUCOSIDE, CITRIC ACID, GLYCERIN, GLYCINE SOJA (SOYBEAN) OIL, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, METHYLPROPANEDIOL, PANTHENOL, PANTOLACTONE, PHENOXYETHANOL, POLYISOBUTENE, SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, SORBITAN OLEATE, TOCOPHEROL, WATER

## **Questions or comments?**

1-866-735-4137

### **PRINCIPLE DISPLAY PANEL - 8 OZ TUBE**

#1 Doctor Recommended  
Sensitive Skincare Brand

Cetaphil®

**Soothing  
Gel Cream**  
with Aloe

Irritated, Sensitive Skin

Fast absorbing formula  
helps rescue, prevent and  
relieve dry, stressed skin

**Skin Protectant Allantoin**

Five Skin Sensitivity Sign

NET WT 8 OZ (226 g)

Distributed By:  
Galderma Laboratories, L.P.  
Fort Worth, TX 76177 USA

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Made in Canada.

cetaphil.com  
P55452-1

**Cetaphil®  
Soothing Gel Cream**

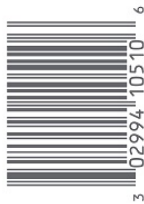
This clinically proven formula contains restorative allantoin to give skin long lasting protection against harsh weather conditions and nourishing aloe vera to instantly cool and soothe severely dry or sunburned skin. The unique, gel-cream texture absorbs quickly for immediate relief so that skin can look and feel healthy.



Trusted by Dermatologists for 75 Years

Drug Facts	
<b>Active Ingredient</b> .....	<b>Purpose</b>
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<b>Uses</b> Temporarily protects minor: • cuts • scrapes • burns ■ helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin	
<b>Warnings</b> 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.	
<b>Directions</b> ■ Apply as needed	
<b>Inactive Ingredients</b> ALOE BARBADENSIS LEAF JUICE POWDER, BUTYROSPERMUM PARKII (SHEA) OIL, CAPRYLYL GLYCOL, CAPRYLYL/CAPRYL GLUCOSIDE, CITRIC ACID, GLYCERIN, GLYCINE SOJA (SOYBEAN) OIL, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, METHYLPROPANEDIOL, PANTHENOL, PANTOLACTONE, PHENOXYETHANOL, POLYISOBUTENE, SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, SORBITAN OLEATE, TOCOPHEROL, WATER	
<b>Questions or comments?</b> 1-866-735-4137	

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RECOMMENDED**  
SENSITIVE SKINCARE BRAND



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Fast absorbing formula  
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Skin Protectant Allantoin



NET WT 8 OZ (226 g)

allantoin cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0299-4105
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	5 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Sheanut Oil</b> (UNII: O88E196QRF)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Caprylyl/Capryl Oligoglucoside</b> (UNII: E00JL9G9K0)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Soybean Oil</b> (UNII: 241ATL177A)	
<b>Sunflower Oil</b> (UNII: 3W1JG795YI)	
<b>Methylpropanediol</b> (UNII: N8F53B3R4R)	
<b>Panthenol</b> (UNII: WW9CM0067Z)	
<b>Pantolactone, (R)-</b> (UNII: J288D700JS)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Polyisobutylene (1000 Mw)</b> (UNII: 5XB3A63Y52)	
<b>Sodium Acrylate/Sodium Acryloyldimethyltaurate Copolymer (400000 Mw)</b> (UNII: 1DXE3F3OZX)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Sorbitan Monooleate</b> (UNII: 06XEA2VD56)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0299-4105-00	10 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	
2	NDC:0299-4105-05	85 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	
3	NDC:0299-4105-10	226 g in 1 TUBE; Type 0: Not a Combination Product	02/17/2020	
4	NDC:0299-4105-15	453 g in 1 JAR; Type 0: Not a Combination Product	02/17/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

OTC monograph final	part347	02/17/2020	
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**Labeler** - Galderma Laboratories, L.P. (047350186)

**Establishment**

Name	Address	ID/FEI	Business Operations
G Production Inc.		251676961	manufacture(0299-4105)

Revised: 3/2022

Galderma Laboratories, L.P.