

## **INFLAMMATION OTC RADIATION RELIEF- allantoin lotion**

### **Skin Deep**

*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 ingredient**

Allantoin (0.5%)

#### **Purpose**

Skin protectant

#### **Uses**

Temporarily protects minor: burns, cuts, and scrapes

Temporarily protects and helps relieve

- chapped skin
- cracked skin

#### **Warnings**

##### **For external use only**

When using this product

- do not get into eyes

##### **Keep out of reach of children**

In case of accidental ingestion seek professional assistance or contact a poison control center immediately.

#### **Directions**

- **Apply as needed**

##### **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

#### **Inactive ingredients**

water, glycerin, helianthus annuus (sunflower) seed oil, glyceryl laurate, glycine soja (soybean) oil, cetearyl alcohol, panthenol, cetareth 20, caprylic/capric triglyceride, sorbitol, cetyl ricinoleate, rosmarinus officinalis (rosemary) leaf, tocopherol, squalane, bisabolol, C10-30 cholesterol/lanosterol

esters, algae extract, sodium carboxymethyl starch, camelia sinensis leaf extract, triticum vulgare (wheat) germ extract, uncaria tomentosa extract, sodium hyaluronate, calendula officinalis flower extract, yeast extract, lavandula angustifolia (lavender) oil, lactobacillus/bean seed extract/sodium glutamate ferment filtrate, petasites japonicus (butterbur) root extract, glycine soja (soybean) seed extract, phytosphingosine HCl, cholesterol, sodium lauroyl lactylate, carbomer, ceramide 3, saccharide isomerate, ceramide 6, ceramide 1, foeniculum vulgare (fennel) fruit extract, saccharomyces/copper ferment, saccharomyces/manganese ferment, saccharomyces/zinc ferment, xanthan gum, glycereth-7 trimethyl ether, phenoxyethanol, iodopropynyl butylcarbamate

### **Questions or comments**

call 1-912-236-9430 weekdays

### **Principal Display Panel**

Inflammation OTC

Radiation Relief

Net wt 1 oz. (28.35 mL)

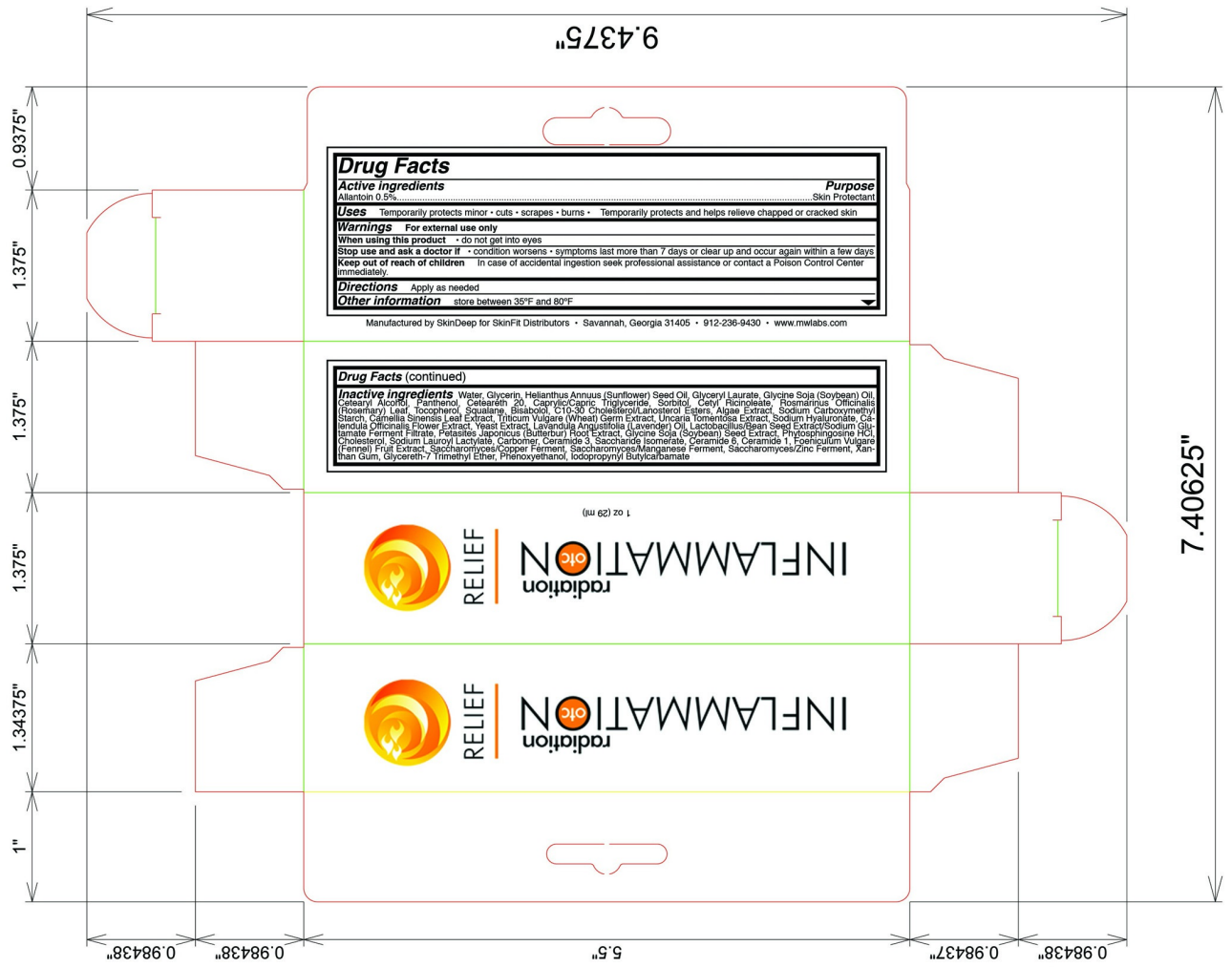
Manufactured by SkinDeep for SkinFit Distributors

Savannah, GA 31405

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[www.mwllabs.com](http://www.mwllabs.com)

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## INFLAMMATION OTC RADIATION RELIEF

allanto in lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45156-5616
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allanto in - UNII:344S277G0Z)	Allanto in	3 g in 600 g

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Helianthus Annuus (UNII: BKJ0J3D1BP)	

<b>Glyceryl Laurate</b> (UNII: Y98611C087)
<b>Soybean Oil</b> (UNII: 241ATL177A)
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)
<b>Dexpanthenol</b> (UNII: 1O6C93RI7Z)
<b>Polyoxyl 20 Cetostearyl Ether</b> (UNII: YRC528SWUY)
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)
<b>Sorbitol</b> (UNII: 506T60A25R)
<b>Ricinoleic Acid</b> (UNII: I2D0F69854)
<b>Rosemary Oil</b> (UNII: 8LGU7VM393)
<b>Alpha-Tocopherol</b> (UNII: H4N855PNZ1)
<b>Squalane</b> (UNII: GW89575KF9)
<b>.Alpha.-Bisabolol, (+/-)-</b> (UNII: 36HQN158VC)
<b>Carrageenan</b> (UNII: 5C69YCD2YJ)
<b>Sodium Starch Glycolate Type A Potato</b> (UNII: 5856J3G2A2)
<b>Green Tea Leaf</b> (UNII: W2ZU1RY8B0)
<b>Triticum Aestivum Pollen</b> (UNII: F1KAH8374D)
<b>Cat's Claw</b> (UNII: 9060PRM18Q)
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45156-5616-2	1 in 1 BOX		
1	NDC:45156-5616-1	29 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/13/2010	

**Labeler** - Skin Deep (833276566)

### Establishment

Name	Address	ID/FEI	Business Operations
Skin Deep		833276566	manufacture

Revised: 1/2011

Skin Deep