

## **COOL MELON - allantoin cream**

**Deb USA, 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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### **Drug Facts**

Active Ingredient

Allantoin, 0.5%

Purpose

Skin protectant

Uses

Helps relieve 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 avoid contact with the eyes.

In case of eye contact, flush with water.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to clean hands

Rub in well

Re-apply after handwashing or as needed

Inactive Ingredients

Water, Cetyl Esters, Petrolatum, Isopropyl Palmitate, Stearyl Alcohol, Cetareth-20, Chloroxylenol, Carbomer, PEG-75 Lanolin, Hydroxyethylcellulose, Methylparaben, Ethanolamine, Propylparaben, Fragrance.

Cool Melon

Medicated Skin Cream

Non-Greasy, Silicone-Free

Conditions and relieves dry, hard-working hands

deb

Proudly made in the USA by Deb

40227-00-100

1 Liter - 33.8 Fluid Ounces



allantoin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11084-042
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
CARBOMER 934 (UNII: Z135WT9208)	
HYDROXYETHYL CELLULOSE (4000 CPS AT 1%) (UNII: ZYD53NBL45)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11084-042-27	1000 mL in 1 BOTTLE, PUMP		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2010	

**Labeler** - Deb USA, Inc. (607378015)

### Establishment

Name	Address	ID/FEI	Business Operations
Deb USA, Inc.		607378015	manufacture