

## **SBS 40 - allantoin lotion**

**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

Temporarily protects and helps relieve chapped or cracked skin

Helps protect from the drying effects of wind and cold weather

Warnings

For external use only

When using this product do not get in eyes

Stop use and ask a doctor if

conditions worsen

symptoms last more than 7 days

or clear up and occur again within a few days

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Keep out of the reach of children

Directions

Apply SBS-40 as needed

Inactive Ingredients

Water, Cetyl Esters, Petrolatum, Isopropyl Palmitate, Stearyl Alcohol, Carbomer, Triethanolamine, Cetareth-20, Chloroxylenol, Methylparaben, Lanolin, Propylparaben, Fragrance, Magnesium Nitrate, Methylchlorisothiazolinone, Magnesium Chloride, Methylisothiazolinone.

deb

SBS 40

Medicated Skin Cream

Skin Protectant

1-Protect

2-Cleanse

3-Restore

85 fl. oz. 2.5 liters

Made in U.S.A.

40108-05-026

Contains a blend of emollients including lanolin to keep skin soft and supple.

Recommended for professionals and individuals who have chapped or cracked hands.

Soothes and protects dry or chapped skin



allantoin lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11084-040
<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)	Allanto in	0.5 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
Cetyl Esters Wax (UNII: D072FFP9GU)	
Petrolatum (UNII: 4T6H12BN9U)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Carbomer 934 (UNII: Z135WT9208)	
Trolamine (UNII: 9O3K93S3TK)	
Chloroxylenol (UNII: 0F32U78V2Q)	
Methylparaben (UNII: A2I8C7HI9T)	
Lanolin (UNII: 7EV65EAW6H)	
Propylparaben (UNII: Z8IX2SC1OH)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
Water (UNII: 059QF0KO0R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:11084-040-08	2500 mL in 1 BOTTLE, PLASTIC		
2	NDC:11084-040-35	148 mL in 1 TUBE		
3	NDC:11084-040-39	30 mL in 1 TUBE		

### 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	01/01/2010	

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

## Establishment

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

Revised: 9/2010

Deb USA, Inc.