

SBS 40- 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.

SBS 40**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

Do not use on

deep or puncture wounds

animal bites

serious burns

When using this product

avoid contact with eyes.

In case of eye contact, flush with water.

Stop use and ask a doctor if

irritation or sensitivity develops

condition worsens

symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

Directions

apply to clean, dry hands as needed

rub in well

Inactive ingredients

Water, Cetyl Esters, Petrolatum, Isopropyl Palmitate, Phenoxyethanol, Stearyl Alcohol, Carbomer,

Triethanolamine, Diazolidinyl Urea, Cetareth-20, Lanolin, Fragrance



deb

SBS 40

Medicated Skin Cream

Silicone-free

Non-irritating

Non-greasy formulation

Helps heal dry hard-working hands

Industry's preferred brand for over 50 years

2.5 Liter

85 Fluid Ounces

USDA Certified Biobased Product

Made in USA

Deb USA, Inc.

Charlotte, NC 28217

1-800-248-7190

www.debgroupp.com

40108

Rev. 01-13

SBS 40

allantoin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11084-240
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 934 (UNII: Z135WT9208)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LANOLIN (UNII: 7EV65EAW6H)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11084-240-08	2500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2013	03/01/2017
2	NDC:11084-240-35	148 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2013	03/01/2017
3	NDC:11084-240-39	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2013	03/01/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2013	

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

Name	Address	ID/FEI	Business Operations
Deb USA, Inc.		078805627	manufacture(11084-240)

Revised: 2/2017

Deb USA, Inc.