SBS 41 MEDICATED CREAM- 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.

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

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, Diazolidinyl

Urea, Ceteareth-20, Carbomer, PEG-75 Lanolin, Hydroxyethylcellulose, Ethanolamine, Fragrance

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

1 Liter

33.8 Fluid Ounces

40127

USDA Certified Biobased Product

Made in USA

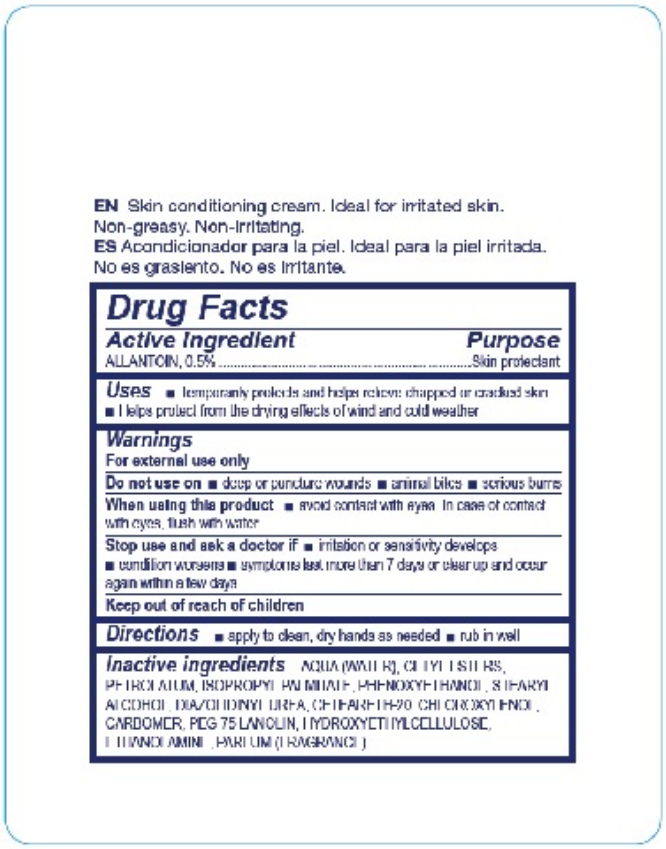
Deb USA, Inc.

Charlotte, NC 28217-1388

1-800-248-7190

www.debgroup.com

Rev. 08-13



SBS 41 MEDICATED CREAM

allantoin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11084-141
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CARBOMER 934 (UNII: Z135WT9208)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (4000 CPS AT 1%) (UNII: ZYD53NBL45)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11084-141-27	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/01/2013	

Labeler - Deb USA, Inc. (607378015)

Establishment

Name	Address	ID/FEI	Business Operations
Deb USA, Inc.		078805627	manufacture(11084-141)

Revised: 10/2017 Deb USA, Inc.