

BOA VIDA CANOPY - dimethicone cream
Central Solutions 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 Ingredients

Dimethicone 2.0% (w/w)

Purpose

Skin protectant

Uses

Helps treat and prevent diaper rash

Protects minor skin irritation due to diaper rash and helps seal out wetness

Temporarily protects and helps relieve chapped or cracked skin

Warnings

For External Use Only

Do not use

on deep or puncture wounds

on animal bites

on serious burns

When using this product

do not get into eyes

Stop use and ask a doctor if

condition worsens

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

Keep out of reach of children

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

Directions

Apply liberally as often as needed

Other Information

Protect from freezing.

Avoid excessive heat

Inactive Ingredients

Water, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cyclotetrasiloxane, Cyclopentasiloxane, Mineral Oil, Isopropyl Palmitate, Ethylhexyl Palmitate, Theobroma Grandiflorum Seed (Cupuacu Butter), Glycerin, Cetyl Dimethicone, Tocopherol (Vitamin E), Beeswax, Diazolidinyl Urea, Hydrogenated Castor Oil, Retinyl Palmitate (Vitamin A), Cholecalciferol (Vitamin D3), Beeswax, Zea Mays Oil, Methyl Paraben, Fragrance, Sodium Chloride

BOA

VIDA

Canopy

skin protectant

helps prevent minor

skin irritation

Formulated

with

Cupuacu Butter

5 fl oz. (148 mL)

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62654-144
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
QUADRO SILAN (UNII: C5KT601WPM)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
THEOBROMA GRANDIFLORUM SEED (UNII: Q7RNT1G37V)	
GLYCERIN (UNII: PDC6A3C0OX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CORN OIL (UNII: 8470G57WFM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62654-144-05	148 mL in 1 BOTTLE, PLASTIC		
2	NDC:62654-144-04	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/01/2011	

Labeler - Central Solutions Inc (007118524)

Establishment

Name	Address	ID/FEI	Business Operations
Central Solutions Inc		007118524	manufacture(62654-144)

Revised: 9/2013

Central Solutions Inc