ALOE VESTA SKIN CONDITIONER - skin conditioner lotion ConvaTec, 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

Dimethicone 3%

Purpose

Skin Protectant

Uses

- Temporarily protects and helps relieve chapped or cracked skin and lips.
- Helps treat and prevent diaper rash.
- Protects minor skin irritation associated with diaper rash and helps seal out wetness.

Warnings

For external use only.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

do not get into eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last 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 consult a Poison Control Center right away.

Directions

For skin protection:

Apply as needed.

For diaper rash:

- Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry.
- Apply liberally, as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged.

Other Information

Store at 15° C - 30° C (59° F - 86° F).

Inactive Ingredients

Water, Petrolatum, Glycerin, Steareth-2, Cetyl Alcohol, Benzyl Alcohol, Laureth-23, Magnesium Aluminum Silicate, Carbomer, Potassium Sorbate, Sodium Hydroxide, Aloe Barbadensis Leaf Juice.

PRINCIPAL DISPLAY PANEL



NDC 43553-3248-4

ConvaTec

ALOE VESTATM

Skin Conditioner 2

MOISTURIZE

SKIN PROTECTANT

Dermatologist Recommended

Fragrance Free

Softens

Moisturizes

NET WT. 4 fl.oz.(118mL)

Case Order No. 324804

ALOE VESTA SKIN CONDITIONER

skin conditioner lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43553-3248
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	.03 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
PETROLATUM (UNII: 4T6H12BN9U)			
GLYCERIN (UNII: PDC6A3C0OX)			
STEARETH-2 (UNII: V56DFE46J5)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
LAURETH-23 (UNII: N72LMW566G)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
CARBOMER 934 (UNII: Z135WT9208)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43553-3248-2	59 mL in 1 BOTTLE		
2	NDC:43553-3248-4	118 mL in 1 BOTTLE		
3	NDC:43553-3248-9	236 mL in 1 BOTTLE		
4	NDC:43553-3248-1	3992 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	04/15/1998		

Labeler - ConvaTec, Inc. (947989757)

Registrant - ConvaTec, Inc. (947989757)

Establishment			
Name	Address	ID/FEI	Business Operations
Guest Packaging LLC		001773076	manufacture

Establishment				
Name	Address	ID/FEI	Business Operations	
Medicia		091396697	manufacture	

Establishment			
Name	Address	ID/FEI	Business Operations
ConvaTec, Inc.		947989757	analysis

Revised: 4/2011 ConvaTec, Inc.