

SENSI CARE MOISTURIZING BODY - petrolatum cream
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 Ingredients

Petrolatum 30%

Dimethicone 1%

Purpose

Skin Protectant

Skin Protectant

Uses

- Temporarily protects minor
- cuts
- scrapes
- burns.

- 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 cream liberally, as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged.

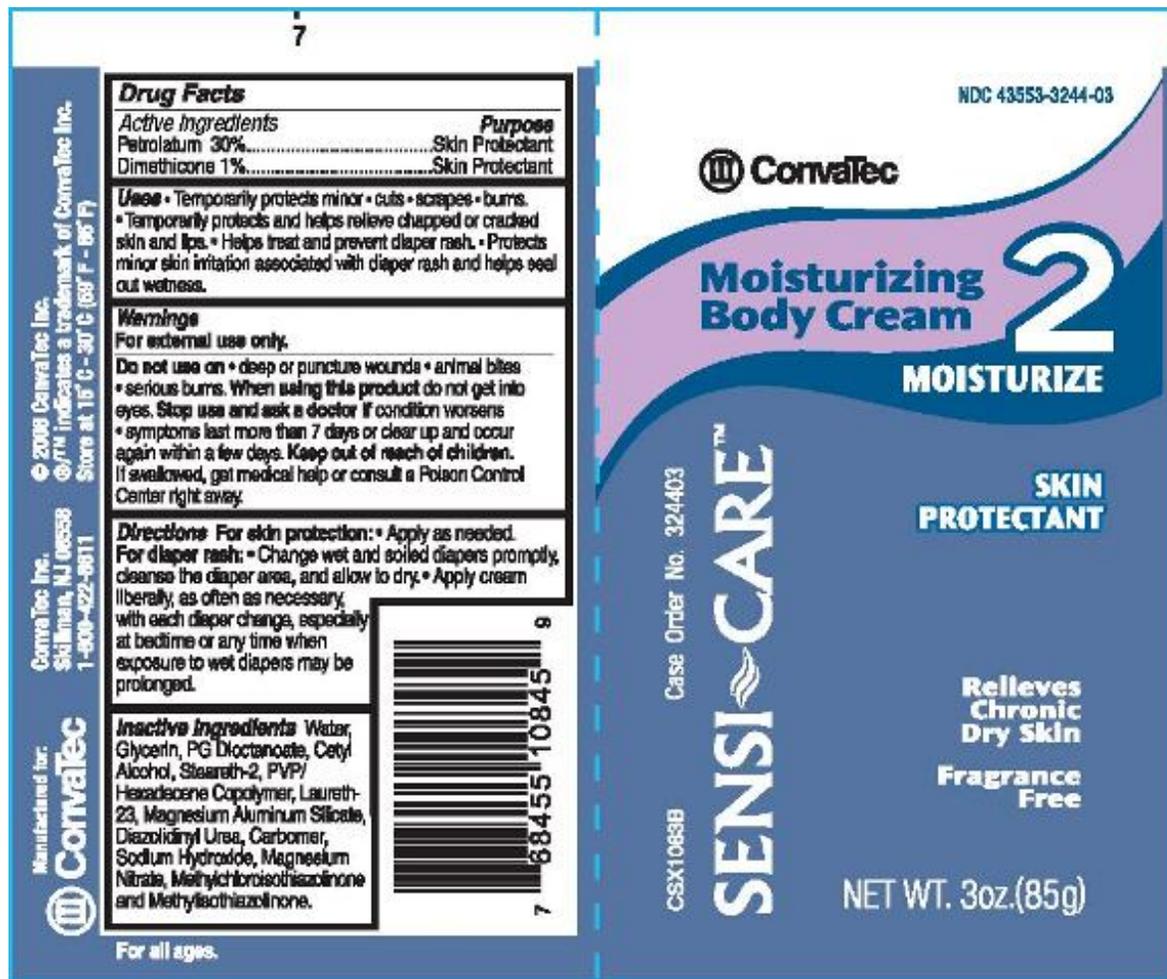
Other Information

Store at 15°C - 30°C (59°F - 86°F).

Inactive Ingredients

Water, Glycerin, PG Dioctanoate, Cetyl Alcohol, Steareth-2, PVP/Hexadecene Copolymer, Laureth-23, Magnesium Aluminum Silicate, Diazolidinyl Urea, Carbomer, Sodium Hydroxide, Magnesium Nitrate, Methylchloroisothiazolinone and Methylisothiazolinone.

PRINCIPAL DISPLAY PANEL



NDC 43553-3244-3

ConvaTec

SENSI~CARE™

Moisturizing Body Cream 2

MOISTURIZE

SKIN PROTECTANT

Relieves Chronic Dry Skin

Fragrance Free

NET WT. 3oz.(85g)

CSX1083B Case Order No. 324403

SENSI CARE MOISTURIZING BODY

petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43553-3244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	300 mg in 1 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL DIETHYLHEXANOATE (UNII: 8D8I9Z0F1Z)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARETH-2 (UNII: V56DFE46J5)	
LAURETH-23 (UNII: N72LMW566G)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics

Color	white (white to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43553-3244-3	85 g in 1 TUBE		

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		00 17730 76	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Medicia		09 13966 97	manufacture

Establishment

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

Revised: 4/2011

ConvaTec, Inc.