## SENSI CARE BODY CREAM- petrolatum, dimethicone cream Guest Packaging LLC.

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.

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#### Sensi Care<sup>TM</sup> Body Cream

#### **Drug Facts**

#### 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.

#### Active ingredients

Petrolatum 30%

Dimethicone 1%

#### Purpose

Skin Protectant

#### **Inactive ingredients**

Water, Glycerin, Cetyl Alcohol, Propylene Glycol Diethylhexanoate, Steareth-2, PVP/Hexadecene Copolymer, Laureth-23, Magnesium Aluminum Silicate, Carbomer, Diazolidinyl Urea, Sodium Hydroxide, Methyl chloroisothiazolinone, Methyl isothiazolinone, Magnesium Chloride, Magnesium Nitrate

**Other information** Store at 15°C -30°C (59°F - 86°F)

#### SENSI-CARE TM

#### **BODY CREAM**

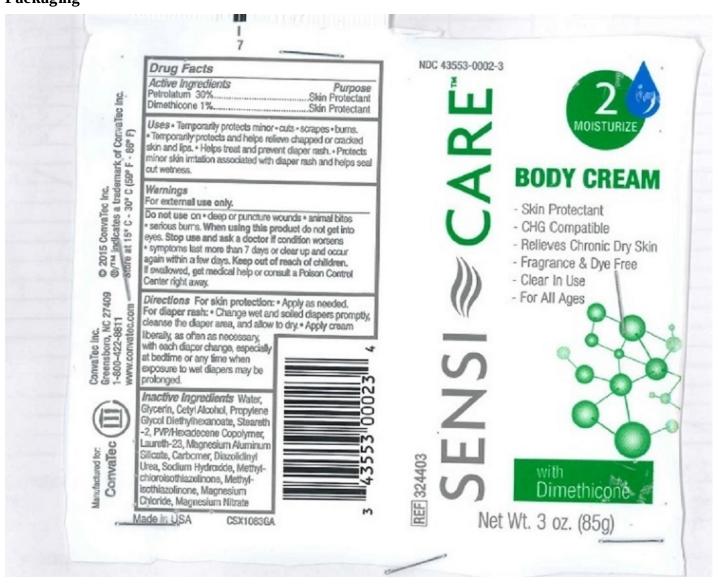
- Skin Protectant
- CHG Compatible
- Relieves Chronic Dry Skin
- Fragrance & Dye Free
- Clear In Use
- For All Ages

## Manufactured for: ConvaTec

ConvaTec Inc. Greensboro, NC 27409 1-800-422-8811 www.convatec.com

#### Made in USA

#### **Packaging**



#### **SENSI CARE BODY CREAM**

petrolatum, dimethicone cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11099-0002

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETHICONE 850 mg in 85 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL DIETHYLHEXANO ATE (UNII: 8 D8 I9 Z0 F1Z)	
STEARETH-2 (UNII: V56 DFE46J5)	
VINYLPYRROLIDO NE/HEXADECENE COPOLYMER (UNII: KFR5QEN0 N9)	
LAURETH-23 (UNII: N72LMW566G)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	

	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>		
1	1 NDC:11099-0002-3	85 g in 1 TUBE; Type 0: Not a Combination Product	06/09/2016			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part347	06/09/2016				

### Labeler - Guest Packaging LLC. (001773076)

Establishment						
Name	Address	ID/FEI	Business Operations			
Guest Packaging LLC.		001773076	manufacture(11099-0002)			

Revised: 6/2016 Guest Packaging LLC.