

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.

Sensi Care™ 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 chlorisothiazolinone, Methyl isothiazolinone, Magnesium Chloride, Magnesium Nitrate

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

SENSI-CARE™

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

Drug Facts

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Petrolatum 30%	Skin Protectant
Dimethicone 1%	Skin Protectant

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Manufactured for:
ConvaTec

Made in USA CSX1083GA

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REF 324403

NDC 43553-0002-3

SENSI-CARE™

2 MOISTURIZE

BODY CREAM

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

with Dimethicone

Net Wt. 3 oz. (85g)

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	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	25.5 g in 85 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	850 mg in 85 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL DIETHYLHEXANOATE (UNII: 8D8I9Z0F1Z)	
STEARETH-2 (UNII: V56DFE46J5)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
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: 229D0E1QFA)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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.