

DIMETHICONE- body shield cream

McKesson

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.

Body Shield Dimethicone

Drug Facts

Active Ingredient

Dimethicone 5%

Purpose

Skin Protectant

Uses

for the treatment and/or prevention of diaper rash
temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only.

When using this product

- do not get into eyes

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

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 contact a poison control center right away.

Directions

- Cleanse skin with Thera Moisturizing Body Cleanser or Thera Foaming Body Cleanser
- Apply cream liberally until entire area is covered
- Apply as needed

Store at 40-95°F (4-35°C)

Inactive Ingredients:

Purified Water, Glyceryl Stearate, PEG 100 Stearate, Stearic Acid, Aleurites Moluccana Seed Oil, Cetyl Alcohol, Glycerin, Butylene Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Dimethicone Crosspolymer, Calcium Pantothenate (Vitamin B5), Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCL (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Starch Octenylsuccinate, Tocopheryl Acetate (Vitamin E), Disodium EDTA, Sodium Hyaluronate, Aloe Barbadensis Leaf Extract, Zingiber Officinale (Ginger) Root Extract, Carthamus Tinctorius (Safflower) Oleosomes, Fragrance, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Bisabolol, Lysine, Histidine, Arginine, Aspartic

Acid,
Threonine, Serine, Glutamic Acid, Proline, Glycine, Alanine, Valine, Methionine, Isoleucine, Leucine,
Tyrosine, Phenylalanine, Cysteine, Triethanolamine

Questions?

Call 1-800-777-4908

NDC 68599-0213-4

McKesson

Thera

DIMETHICONE BODY SHIELD

Provides mild skin protection against irritation from chapped or cracked skin.

Single Patient Use

NET CONTENTS 4 fl oz (118 mL)

MFR # 53-DS4

NDC 68599-0213-4

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BODY SHIELD**

MOISTURIZES HELPS PROTECT HELPS PREVENT HELPS TREAT

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THERAPY
for your skin

MCKESSON

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Thera® is a specially formulated skin care line that helps restore skin to a healthy condition.
Store at 40-95°F (4-35°C).
Questions? Call 1-800-777-4908
Distributed by McKesson Medical-Surgical Inc.
Richmond, VA 23233 FVN E0619 Made in USA

ROOM NO.

NAME

DIMETHICONE

body shield cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68599-0213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 ug in 1 mg
Inactive Ingredients		
Ingredient Name	Strength	
VALINE (UNII: HG18B9YRS7)		
PHENYLALANINE (UNII: 47E5O17Y3R)		
CYSTEINE (UNII: K848JZ4886)		
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)		
KUKUI NUT OIL (UNII: TP11QR7B8R)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)		
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)		
OCTENYLSUCCINIC ACID (UNII: 12UZE4X73L)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
PROLINE (UNII: 9DLQ4CIU6V)		
GLYCINE (UNII: TE7660XO1C)		
ARGININE (UNII: 94ZLA3W45F)		
ASPARTIC ACID (UNII: 30KYC7MIA)		
ALANINE (UNII: OF5P57N2ZX)		
LEUCINE (UNII: GMW67QNF9C)		
TYROSINE (UNII: 42HK56048U)		
METHIONINE (UNII: AE28F7PNPL)		
TROLAMINE (UNII: 9O3K93S3TK)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)		
HYALURONATE SODIUM (UNII: YSE9PPT4TH)		
GINGER (UNII: C5529G5JPQ)		
LYSINE (UNII: K3Z4F929H6)		
THREONINE (UNII: 2ZD004190S)		
GLUTAMIC ACID (UNII: 3KX376GY7L)		
ISOLEUCINE (UNII: 04Y7590D77)		
PEG-100 STEARATE (UNII: YD01N1999R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
NIACINAMIDE (UNII: 25X5118RD4)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
HISTIDINE (UNII: 4QD397987E)		

SERINE (UNII: 452VLY9402)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-0213-4	118 mg in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/12/2019	

Labeler - McKesson (023904428)

Establishment

Name	Address	ID/FEI	Business Operations
Central Solutions		007118524	manufacture(68599-0213)

Revised: 1/2021

McKesson