

## **DIMETHICONE- skin protectant 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.*

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### **Moisturizing body cream**

#### **Drug Facts**

##### **Active Ingredient:**

Dimethicone 1.75%

##### **Purpose**

Skin Protectant

##### **Uses**

Temporarily protects and helps relieve chapped or cracked skin beneficial for face, hands, body and legs

##### **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**

Apply cream liberally as needed

Store at 40-95°F (4-35°C).

##### **Inactive Ingredients:**

Purified Water, Aleurites Moluccana Seed Oil, Stearic Acid, Cetyl Alcohol, Glycerin, Glyceryl Stearate, PEG 100 Stearate, Carthamus Tinctorius (Safflower) Seed Oil, Dimethicone Crosspolymer, Butylene Glycol, Sodium Hyaluronate, Aloe Barbadensis Leaf Extract, Zingiber Officinale (Ginger) Root Extract, Carthamus Tinctorius (Safflower) Oleosomes, 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), Bisabolol, Lysine, Histidine, Arginine, Aspartic Acid, Threonine, Serine, Glutamic Acid, Proline, Glycine, Alanine, Valine, Methionine, Isoleucine, Leucine, Tyrosine, Phenylalanine, Cysteine, Fragrance, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Disodium EDTA, Triethanolamine

**Questions?**

Call 1-800-777-4908

NDC 68599-0218-4

McKesson

Thera

MOISTURIZING BODY CREAM


Everyday moisturizer and skin conditioner.

Single Patient Use


NET CONTENTS 4 fl oz (118 mL)

MFR # 53-CRM4

NDC 68599-0218-4





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**Thera**

MOISTURIZING  
BODY CREAM

  
MOISTURIZES

  
HELPS PROTECT

  
HELPS PREVENT

  
HELPS TREAT

Everyday moisturizer and skin conditioner.

Single Patient Use

**THERAPY**

*for your skin*

**McKesson**

NET CONTENTS 4 fl oz (118 mL)  
MFR # 53-CRM4

ROOM NO.

NAME

**Drug Facts**

Active ingredient	Purpose
Dimethicone 1.75%	Skin Protectant

**Uses** ■ temporarily protects and helps relieve chapped or cracked skin ■ beneficial for face, hands, body and legs

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**Directions** ■ Apply cream liberally as needed

**Inactive ingredients**

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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 PVN E0819 Made in USA

NDC 68599-0218-8

McKesson

Thera

MOISTURIZING BODY CREAM

Everyday moisturizer and skin conditioner.

Single Patient Use  
 NET CONTENTS 32 fl oz (946 mL)  
 MFR # 53-CRM32

NDC 68599-0218-8

*Thera*

MOISTURIZING  
 BODY CREAM



Everyday moisturizer and  
 skin conditioner.

Single Patient Use

**THERAPY**  
*for your skin*

**McKesson**

NET CONTENTS 32 fl oz (946 mL)  
 MFR # 53-CRM32

Drug Facts	
Active ingredient	Purpose
Dimethicone 1.75%	Skin Protectant
<b>Uses</b> ■ temporarily protects and helps relieve chapped or cracked skin ■ beneficial for face, hands, body and legs	
<b>Warnings</b> For external use only. 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 Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.	
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<b>Inactive ingredients</b> Purified Water, Aleurites Moluccana Seed Oil, Stearic Acid, Cetyl Alcohol, Glycerin, Glyceryl Stearate, PEG 100 Stearate, Carthamus Tinctorius (Safflower) Seed Oil, Dimethicone Crosspolymer, Butylene Glycol, Sodium Hyaluronate, Aloe Barbadosensis Leaf Extract, Zingiber Officinale (Ginger) Root Extract, Carthamus Tinctorius (Safflower) Oleosomes, Calcium Pantothenate (Vitamin B5), Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCl (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Starch Octylsuccinate, Tocopheryl Acetate (Vitamin E), Bisabolol, Lysine, Histidine, Arginine, Aspartic Acid, Threonine, Serine, Glutamic Acid, Proline, Glycine, Alanine, Valine, Methionine, Isoleucine, Leucine, Tyrosine, Phenylalanine, Cysteine, Fragrance, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Disodium EDTA, Triethanolamine.	

ROOM NO.

NAME

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Distributed by  
 McKesson Medical-Surgical Inc.  
 Richmond, VA 23233  
 PVN D0819 Made in USA



NDC 68599-0218-1  
 McKesson  
 Thera  
 MOISTURIZING BODY CREAM  
 Refill for McKesson Pump Dispenser MFR # 53-1000.  
 NET CONTENTS 1000 mL (34 fl. oz.)  
 MFR # 53-CRM1000

NDC 68599-0218-1

# Thera<sup>®</sup>

## MOISTURIZING BODY CREAM



MOISTURIZES



HELPS PROTECT



HELPS PREVENT



HELPS TREAT

Refill for McKesson Pump  
Dispenser MFR # 53-1000.

Single Patient Use

### McKesson

NET CONTENTS 1000 mL (34 fl oz)

MFR # 53-CRM1000

### Drug Facts

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Dimethicone 1.75%	Skin Protectant

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1 2 4 7 9 1 2 0 3 8 6

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Richmond, VA 23233  
PVN D0819 Made in USA

## DIMETHICONE

skin protectant cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68599-0218
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	17.5 ug in 1 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>KUKUI NUT OIL</b> (UNII: TP11QR7B8R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GINGER</b> (UNII: C5529G5JPQ)	
<b>CARTHAMUS TINCTORIUS FLOWER BUD</b> (UNII: B86IS27400)	
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>ARGININE</b> (UNII: 94ZLA3W45F)	
<b>ASPARTIC ACID</b> (UNII: 30KYC7MIAI)	
<b>PROLINE</b> (UNII: 9DLQ4CIU6V)	

<b>METHIONINE</b> (UNII: AE28F7PNPL)
<b>SERINE</b> (UNII: 452VLY9402)
<b>ALANINE</b> (UNII: OF5P57N2ZX)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>CARTHAMUS TINCTORIUS FLOWER OIL</b> (UNII: SDQ136WMM5)
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>THREONINE</b> (UNII: 2ZD004190S)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>OCTENYLSUCCINIC ACID</b> (UNII: 12UZE4X73L)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>VALINE</b> (UNII: HG18B9YRS7)
<b>ISOLEUCINE</b> (UNII: 04Y7590D77)
<b>PHENYLALANINE</b> (UNII: 47E5O17Y3R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>LYSINE</b> (UNII: K3Z4F929H6)
<b>HISTIDINE</b> (UNII: 4QD397987E)
<b>GLUTAMIC ACID</b> (UNII: 3KX376GY7L)
<b>GLYCINE</b> (UNII: TE7660XO1C)
<b>LEUCINE</b> (UNII: GMW67QNF9C)
<b>CYSTEINE</b> (UNII: K848JZ4886)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)
<b>TYROSINE</b> (UNII: 42HK56048U)
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-0218-4	118 mg in 1 TUBE; Type 0: Not a Combination Product	11/04/2019	
2	NDC:68599-0218-8	946 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2019	
3	NDC:68599-0218-1	1000 mg in 1 BAG; Type 0: Not a Combination Product	11/04/2019	01/01/2022

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	11/04/2019	

**Labeler** - McKesson (023904428)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Central Solutions		007118524	manufacture(68599-0218)

Revised: 9/2021

McKesson