

SIMPLY FIRM - BODY GELCREME- dimethicone gel
CarePlus Pharma S.A. de C.V.

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.

Active Ingredients.....Purpose

Dimethicone 1%.....Skin Protectant

Uses: protects from minor skin irritations.

- temporarily protects injured or exposed skin
- slows the loss of water of the skin by forming a barrier on the skin's surface
- enhances the appearance of dry or damaged skin
- increases the water content of the top layers of the skin
- is a lubricant for the surface of the skin
- gives skin a soft and smooth appearance

Warnings: For external use only

- when using this product skin irritation may occur
- some medicines may interact with dimethicone, however, no specific interactions are known at this time

Do not use

- if you are allergic to any ingredients listed
- if you have sensitive skin and/or are sensitive to Dimethicone
- do not use if you are pregnant, planning to become pregnant, or breast feeding
- if you have an open wound, burn, damaged or irritated skin

When using this product

- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling
- should irritation occur lesson frequency of use
- avoid unnecessary sun exposure and use a 45 SPF sun screen when going outside

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
- any of these severe effects occur; allergic reaction, irritation becomes severe i.e. persistent rash, hives, itching, burning, difficulty breathing, swelling

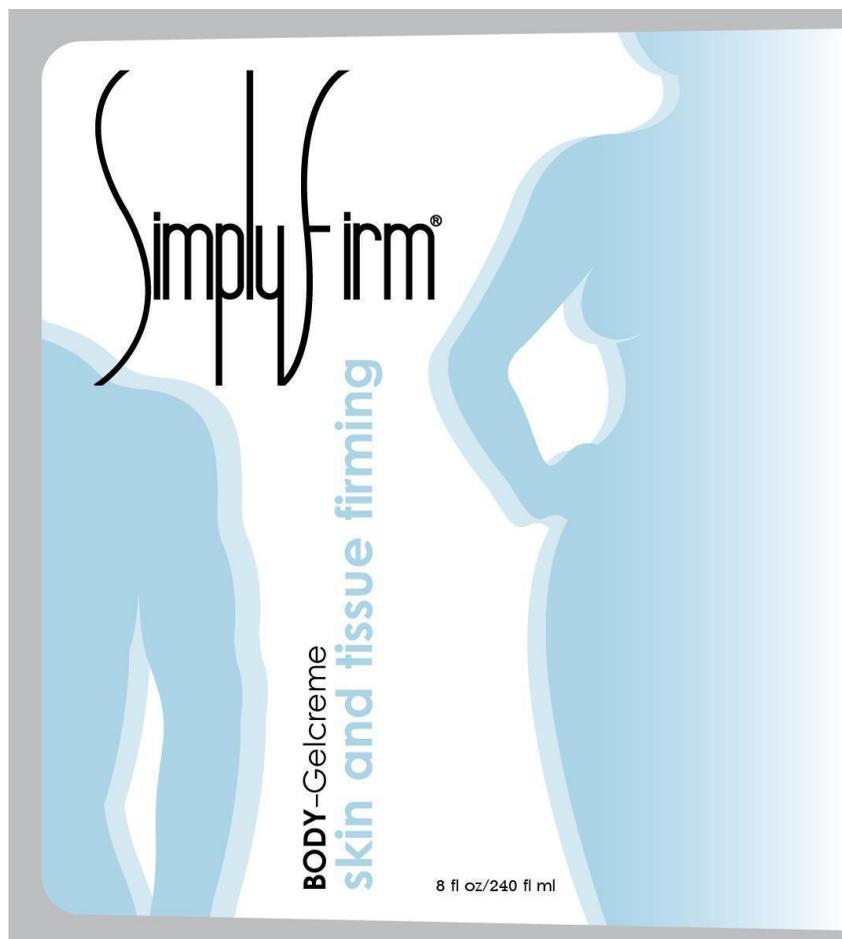
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately

Directions:

- cleanse gently
- apply to body
- massage into desired area using long upward strokes
- start with a single application, gradually increase to as many applications as desired
- when going outside be sure to use a 45 SPF SUN SCREEN applicable to the area
- if excessive irritation or sensitivity develops stop use of product and contact a physician

Other ingredients: Water, Almond Oil, Glycerin, Cetearyl alcohol, Cetearteh-12, almond Oil, L-Carnitine, DMAE, Bitartrate, Sodium Ascorbyl Fosphate,, Sunflower Seed Oil, Green Tea extract, Coffee extract, Sodium Dodecyl Sulphate, Base Lemon Grass, Pepermint Oil, Menthol, Ultrex 21, Green Tea scent, EDTA, BHT, BHA.

8 fl oz / 240 fl ml



DRUG FACTS	
Active Ingredients: Dimethicone 1 %	Purpose: Skin protectant
Uses: Protects from skin irritations • temporary protects injured or exposed skin • slows the loss water of the skin by forming a barrier on the skin's surface • enhances the appearance of dry or damaged skin • increases the moisture content of top layers of the skin • is a lubricant for the surface of the skin • gives skin a soft and smooth appearance	
Warnings: For external use only • When using this product skin irritation may occur • some medicines may interact with Dimethicone, however, no specific • interactions are known at this time	
Do not use • on deep or puncture wounds • on animal bites • on serious burns • if you are allergic to any ingredients listed • if you have sensitive skin / or are sensitive to Dimethicone • if you have an open wound, burn, damaged or irritated skin	
When using this product • do not get into eyes • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling • should irritation occur lessen frequency of use • avoid unnecessary sun exposure and use a 45 SPF sun screen when going outside	
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 • any of these severe side effects occur; allergic reaction, irritation becomes severe i.e. persistent rash, hives, itching, burning, difficulty breathing, swelling	
If pregnant or breast feeding, ask a health professional before use Keep out of the reach of children, if swallowed get medical help or contact a Poison Control Center immediately.	
Directions: • cleanse gently • apply to body • massage gently in an upward motion • start with a single application, gradually increase to as many applications as desired, apply as needed • when going outside be sure to use a sun screen • if excessive irritation or sensitivity develops stop use of product and contact a physician	
Inactive ingredients: Water, Almond Oil, Glycerin, Ceteraryl alcohol, Cetearth-12, Almond Oil, L-Carnitine, DMAE, bitartase, Sodium Ascorbyl Phosfate, Sunflower seed oil, Trietanolamine, Base almond, Ultrex 21, Ascorbic acid, Sodium Dodecyl Sulfate, Base Lemon Grass, Coffee extract, Peppermint oil, Base mint, Chocolate scent, Green Tea scent, Green Tea extract, Metylparaben, Propilparaben, EDTA, BHT, BHA	

Developed and Manufactured by:
 CarePlus Pharma S.A. de C.V. Via Rápida Oriente
 11812-B, Col. Mineral de Santa Fe, C.P. 22360,
 Tijuana, B.C., R.F.C. CPH 041104 MGS
 REG: COFEPRIS, México

Lote:
Exp:



Simply Firm Body - GelcremeSkin and tissue firming

SIMPLY FIRM - BODY GELCREME

dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51439-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	.0024 mg in .024 mg

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
ALMOND OIL (UNII: 66YXD4DKO9)	
LEVO CARNITINE (UNII: 0G389FZZ9M)	
DEANOL (UNII: 2N6K9DRA24)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MINT (UNII: FV98Z8GITP)	
ALMOND (UNII: 3Z252A2K9G)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
EDETIC ACID (UNII: 9G34HU7RV0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51439-003-01	.024 mg in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/05/2012	

Labeler - CarePluss Pharma S.A. de C.V. (815061551)

Registrant - CarePluss Pharma S.A. de C.V. (815061551)

Establishment

Name	Address	ID/FEI	Business Operations
CarePluss Pharma S.A. de C.V.		815061551	manufacture(51439-003)