

SIMPLY FIRM - FACE AND NECK NON SURGICAL FACE LIFT- 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 Ingredient 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 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 any of these severe side effects occur: allergic reaction, irritation become 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 SIMPLY FIRM 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, Mineral Oil, L-Carnitine, DMAE bitartrate, Sodium Ascorbyl Fosphate, Carbomer, Green Tea extract, Coffe Berry extract, Trietanolamine, Sodium Lauryl Sulphate, Vitamin C, Pepermint Oil, Menthol, Almond scent, Green Tea scent, Coco scent, EDTA disodium.

3 fl oz / 119 mL

Endless Youth and Life

Simply Firm®

NON-SURGICAL FACELIFT
FACE & NECK
CRÈME

Exclusively formulated for and Distributed by
Endless Youth and Life
452 N. Bedford Dr., Beverly Hills, CA 90210
to reorder call 1-800-303-8382
www.endlessyouthandlife.com

Manufactured by:
CarePlus Pharma S.A. de C.V.
Avenida de los Charros # 5-A
Frac. José Sandoval C.P. 22450,
Tijuana, B.C.
R.F.C. CPH 041104 MG5.
Reg. COFEPRIS, Mexico



Lot:
Exp:



4 fl oz/119ml

Drug Facts:	
Active Ingredients: Dimethicone 1%	Purpose: Skin protectant
Uses: Protects from minor skin irritations temporarily protects injured or exposed skin prevents the loss of moisture 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 top layers of the skin acts as 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. if irritation occurs, lessening frequency of use avoid unnecessary sun exposure and use a 45 SPF sun screen when going outside	
Stop use and ask a doctor if any of these severe side effects occur; allergic reaction, irritation becomes severe i.e. persistent rash, hives, itching, burning, difficulty breathing, swelling	
Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center immediately.	
Directions: cleanse gently apply SIMPLY FIRM FACE/NECK to desired area massage in 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 specific to the area if excessive irritation or sensitivity develops stop use of product and contact a physician	
Other Ingredients: Stearic acid, Almond Oil, Glycerin, Cetearyl alcohol, Ceteareth-12, Mineral Oil, BHT/BHA, L-Carnitine, DMAE bitartrate, Sodium Ascorbyl Phosphate, Coffee Berry extract, Green Tea extract, Triethylamine, Sodium Lauryl Sulphate, Vitamin C, Papernut Oil, Menthyl, Hyaluronic acid, Almond scent, Green Tea scent, Chocolate/Coffee scent, EDTA disodium.	
Questions, comments complaints: 619-734-2383 contact@careplus.com	

SIMPLY FIRM - FACE AND NECK NON SURGICAL FACE LIFT

dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51439-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	.00119 mg in .119 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
MINERAL OIL (UNII: T5L8T28FGP)	
LEVO CARNITINE (UNII: 0G389FZZ9M)	
DEANOL (UNII: 2N6K9DRA24)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

GREEN TEA LEAF (UNII: W2ZU1RY8B0)
COFFEE BEAN (UNII: JFH385Y744)
TROLAMINE (UNII: 9O3K93S3TK)
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
PEPPERMINT OIL (UNII: AV092KU4JH)
MINT (UNII: FV98Z8G1TP)
ALMOND (UNII: 3Z252A2K9G)
MELISSA OFFICINALIS (UNII: YF70189L0N)
COCOA (UNII: D9108TZ9KG)
EDETIC ACID (UNII: 9G34HU7RV0)
METHYL PARABEN (UNII: A218C7H9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
SUNFLOWER OIL (UNII: 3W1JG795Y)
WATER (UNII: 059QF0KO0R)
POMEGRANATE SEED OIL (UNII: 0U45XV0T6)
CARBOMER HOMO POLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51439-002-01	.119 mg in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/27/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
CarePlus Pharma S.A. de C.V.		815061551	manufacture(51439-002)

Revised: 4/2013

CarePlus Pharma S.A. de C.V.