PLAGENTRA MOTHERS BELLY- dimethicone lotion C.A Pharm Co., Ltd.

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

Active Ingredient: Dimethicone 2%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Glycerin, Caprylic/Capric Triglyceride, Saccharomyces Ferment Filtrate, Dipropylene Glycol, Ethylhexyl Palmitate, Hydrogenated Polydecene, 1,2-Hexanediol, Polyglutamic Acid, Leuconostoc/Radish Root Ferment Filtrate, Stearic Acid, Tri-C14-15 Alkyl Citrate, Cetearyl Olivate, Sorbitan Olivate, Butylene Glycol, Cyclopentasiloxane, Cyclohexasiloxane, Sodium Hyaluronate, Musa Sapientum (Banana) Fruit Extract, Centella Asiatica Extract, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Polygonum Cuspidatum Root Extract, Scutellaria Baicalensis Root Extract, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Chamomilla Recutita(Matricaria) Flower Extract, Rosmarinus Offcinalis (Rosemary) Leaf Extract, Glyceryl Stearate, Carbomer, Ethoxydiglycol, Disodium EDTA, Potassium Hydroxide

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings:

- 1. Stop using the product and go to a doctor immediately if one of the following symptoms occurs. If immediate care is not sought, the symptoms may worsen:
- 1) Itching, redness, swelling, rash, etc. 2) If one of the symptoms above occurs due to direct sunlight.
- 2. Do not apply the product to wounds or skin with dermatitis such as eczema.
- 3. Storage and Handling, 1) Keep the lid closed after use. 2) Keep the product out of children's reach. 3) Keep away from direct sunlight, do not store at high or low temperature.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of babies and children.

INDICATIONS & USAGE

Indication and usage:

1) Tighten the lid after using it. 2) Don't keep it in the place where the temperature is extremely hot or low and exposed to the direct sunlight. 3) Use it in the morning or evening after shower.

DOSAGE & ADMINISTRATION

Dosage and administration:

Take appropriate amount to the entire face and body, gently massage and tapping until absorbed.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





dimethicone lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68988-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)

Dimethicone

3 mg in 150 mL

Inactive Ingredients

Ingredient Name Strength

Water (UNII: 059QF0KO0R)

Glycerin (UNII: PDC6A3C0OX)

Packaging

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ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:68988-010-01	150 mL in 1 CARTON				

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part347	0 4/0 1/20 14				

Labeler - C.A Pharm Co., Ltd. (688198385)

Registrant - C.A Pharm Co., Ltd. (688198385)

Establishment							
Name	Address	ID/FEI	Business Operations				
C.A Pharm Co., Ltd.		688198385	manufacture(68988-010)				

Revised: 12/2014 C.A Pharm Co., Ltd.