PLAGENTRA BABY SOOTHING RELIEF- dimethicone cream 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, Zinc Oxide, Propanediol, Hydrogenated Polydecene, Dimethicone Crosspolymer, Cyclopentasiloxane, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Betaine, Tri-C14-15 Alkyl Citrate, Polyglutamic Acid, Stearic Acid, Glyceryl Stearate, Phaseolus Radiatus Extract, Betula Platyphylla Japonica Bark Extract, Rumex Crispus Root Extract, Scutellaria Baicalensis Root Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Polygonum Cuspidatum Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Camellia Sinensis Leaf Extract, Centella Asiatica Extract, Sorbitan Olivate, Cetearyl Olivate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Caprylic/Capric Glycerides, Caprylyl Glycol, Disodium EDTA, Butylene Glycol, Leuconostoc/Radish Root Ferment Filtrate, Fragrance

PURPOSE

Purpose: Skin Portectant

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.

4. It contains AHA. If it is your first time to use this product, take a small amount and gently apply to the skin to check if it cause andy trouble to your skin.

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.

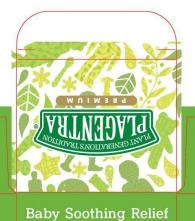
2) Don't keep it in the place where the temperature is extremely hot or low and exposed to the direct sunlight.

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











MADE IN KOREA



Baby Soothing Relief Cream



MOMBY 0_0

Baby Soothing Relief





PLAGENTRA BABY SOOTHING RELIEF

dimethicone cream

Product Information	on								
Product Type		HUMAN OTC DRUG	Item Code (Source)			NDC:68988-100			
Route of Administrati	on	TOPICAL							
Active Ingredient/Active Moiety									
Ingredient Name					Basis of Strength		Strength		
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)					Dimethicone 1.6 g in 80 g			1.6 g in 80 g	
Inactive Ingredients									
Ingredient Name						Strength			
Water (UNII: 059QF0K00R)						ourigen			
Zinc Oxide (UNII: SOI2LOH54Z)									
Packaging									
# Item Code	Pac	kage Description	Marketi	Marketing Start Date		Marketing		g End Date	
1 NDC:68988-100-01	80 g in 1	CARTON							
Marketing Information									
Marketing Category	Application Number or Monograph Citation M			Marke	Marketing Start Date		Marketing End Date		
OTC monograph final	part347			04/01/2014					

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(68988-100)

Revised: 12/2014

C.A Pharm Co., Ltd.