

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 Oliviate, Cetearyl Oliviate, 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 any 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



Baby Soothing Relief

Baby Soothing Relief



Active Ingredients :
Dimethicone 2,000 % (W/W)

Inactive Ingredients :
Water, Zinc Oxide, Proxanediol, Hydrogenated Polydecene, Dimethicone Crosspolymer, Cyclopentasiloxane, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Betaine, Tri-C14-15 Alkyl Citrate, Polyglutamic Acid, Stearic Acid, Glyceryl Stearate, Phaseolus Radicatus 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 Olivatate, Cetearyl Olivatate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Caprylic/Capric Glycerides, Caprylyl Glycol, Disodium EDTA, Butylene Glycol, Leuconostoc /Radish Root Ferment Filtrate, Fragrance

Purpose: Skin Protectant
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 babies and children.



MADE IN KOREA



Baby Soothing Relief Cream

Contain patent ingredient of BSASM for make a baby's health skin and high-moisture PGA ingredient maintain moist skin for a long time.

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 bathing.

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

Consumer Compensation Policy :
If any defect is found, compensation, refund or exchange will be offered in accordance with the Consumer Dispute Resolution Standard of Fair Trade Commission.

*Please refer the user guide and warnings of instructions before use.

Manufactured for WINNOVA CO.,LTD
14-6, Gajang Industry dong-ro, Osan, Gyeonggi-do, Korea.

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The 36th Golden Prize at the International Exhibition of Inventions in Geneva.

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PLAGENTRA BABY SOOTHING RELIEF
dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68988-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	1.6 g in 80 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Zinc Oxide (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68988-100-01	80 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	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.