PLAGENTRA BABY BUBBLE WASH- allantoin aerosol, foam
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: Allantoin 0.5%

INACTIVE INGREDIENT

Inactive Ingredients:
Water, Potassium Laureth Phosphate, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Glycerin, Polyglutamic Acid, Leuconostoc/Radish Root Ferment Filtrate, Butylene Glycol, Phaseolus Radiatus Extract, Betula Platyphylla Japonica Bark Extract, Rumex Crispus Root Extract, Camellia Sinensis Leaf Extract, Betaine, Sodium Benzoate, Citric Acid, Disodium EDTA, 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.

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 in the bath.

DOSAGE & ADMINISTRATION

Dosage and administration:
Take appropriate amount and gently apply to the body.
Then wash it up with.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PLAGENTRA BABY BUBBLE WASH

allantoin aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68988-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	Allantoin	1.25 mg in 250 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68988-080-01	250 mL 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(68988-080)

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