

PARMA ANUS SKIN PREMIUM CLEANSER- allantoin gel
PARMA KOREA.CO.LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

71614-002_Parma Anus Skin Premium Cleanser

Allantoin 0.3%

Skin Protectant

Anus Cleansing

Wet anal area thoroughly.

Apply an appropriate amount of the product to anal area. Massage anus and maintain 30 seconds. Rinse with water for 60 seconds.

For external use only.

Do not use on damaged or broken skin.

Rinse with water to remove.

Stop use and ask a doctor if rash or irritation occurs.

Keep out of reach of children

Water

Hydroxyethylcellulose

Black Strap Powder

Mandelic Acid

Disodium EDTA

Oleic Acid

Lauryl Glucoside

Butylene Glycol

Diglycerin

Sodium Cocoate

Cocamide MIPA

sh-Oligopeptide-1

Acetyl Hexapeptide-8

Shea Butteramidopropyl Betaine

Sodium Cocoamphoacetate

Oryza Sativa (Rice) Bran Extract

Artemisia Vulgaris Extract

Phaseolus Radiatus Seed Extract

Centella Asiatica Extract

Portulaca Oleracea Extract

Crataegus Oxyacantha Extract

Rheum Palmatum Root Extract

Bambusa Vulgaris Extract

Eucalyptus Globulus Leaf Extract

Hamamelis Virginiana (Witch Hazel) Extract
 Chamomilla Recutita (Matricaria) Flower/Leaf Extract
 Propolis Extract
 Sapindus Mukorossi Fruit Extract
 Panax Ginseng Root Extract
 Polysorbate 85
 1,2-Hexanediol
 Caprylic/Capric Triglyceride
 Fragrance



PARMA ANUS SKIN PREMIUM CLEANSER

allantoin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71614-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
		Ingredient Name	Basis of Strength	Strength
		ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	3 mg in 1 mL
Inactive Ingredients				
		Ingredient Name	Strength	
		WATER (UNII: 059QF0KO0R)		
		HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)		
		MANDELIC ACID (UNII: NH496X0UJX)		
		EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
		OLEIC ACID (UNII: 2UMI9U37CP)		
		LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)		
		BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
		DIGLYCERIN (UNII: 3YC120743U)		
		SODIUM COCOATE (UNII: R1TQH25F4I)		
		COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)		
		NEPIDERMIN (UNII: TZK30RF92W)		
		ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWL)		
		SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)		
		RICE BRAN (UNII: R60QEP13IC)		
		ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)		
		MUNG BEAN (UNII: 1LIB31N73G)		
		CENTELLA ASIATICA (UNII: 7M867G6T1U)		
		PURSLANE (UNII: M6S840WYG5)		
		RHEUM PALMATUM ROOT (UNII: G025DAL7CE)		
		BAMBUSA VULGARIS TOP (UNII: FIW80T6P6V)		
		EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)		
		HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)		
		MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)		
		PROPOLIS WAX (UNII: 6Y8XYV2NOF)		
		SAPINDUS MUKOROSI FRUIT (UNII: 66H9NW427Y)		
		ASIAN GINSENG (UNII: CUQ3A77YXI)		
		POLYSORBATE 85 (UNII: A7F3N56197)		
		1,2-HEXANEDIOL (UNII: TR046Y3K1G)		
		MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71614-002-02	1 in 1 CARTON	08/27/2018	
1	NDC:71614-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing	Application Number or Monograph		Marketing Start	Marketing End

Category	Citation	Date	Date
unapproved drug other		08/27/2018	

Labeler - PARMA KOREA.CO.LTD (694857393)

Registrant - PARMA KOREA.CO.LTD (694857393)

Establishment

Name	Address	ID/FEI	Business Operations
PARMA KOREA.CO.LTD		694857393	manufacture(71614-002)

Revised: 1/2023

PARMA KOREA.CO.LTD