

FAREWELL COLLECTION- antiseptic shower cream cream
Brisas del Caribe Corp.

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.

Brisas-Paveemol Shower Cream nut Label

Active Ingredient(s)

Benzalkonium chloride 0.05 %.

Purpose

Antiseptic

Use

To help reduce bacteria on hands.

Warnings

For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away 1 800-222-1222

Directions

- Apply on skin thoroughly, wash, and rinse. Suitable to daily use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15 and 30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

acrylates copolymer, aloe barbadensis leaf extract, chlorphenesin, cocamidopropyl betaine, disodium EDTA, glycerin, glycol distearate, maltodextrin, phenoxyethanol, polyquaternium-7, propylene glycol, purified water USP, shea butter, sodium benzoate, sodium coco-sulfate, sodium laureth sulfate, triethanolamine.

Package Label - Principal Display Panel

Moisturizing Antiseptic Shower Cream

Our Antiseptic Liquid Shower Cream cleanses your skin of harmful germs and bacteria. Specially formulated with Benzalkonium Chloride to protect your skin and provide maximum care and moisture. This product gives you the confidence and protection you need for yourself and your family. Say FAREWELL to all germs and bacteria!

Say FAREWELL to all germs and bacteria!

Distributed by
Brisas del Caribe Corp
Carr 188 Km 0.7
San Isidro Ind Park
Canóvanas, PR 00729
happypetpr.com

  
Made in Thailand





Moisturizing Antiseptic Shower Cream

with Aloe Vera & Glycerin
Leaves Skin Soft & Clean
Alcohol-Free Antiseptic Lotion
MACADAMIA NUT

Net: 250 mL e 8.5 OZ

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride 0.05%	Antiseptic

Uses
To help reduce bacteria on the skin.

Warnings
For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away at 1-800-222-1222.

Directions

- Apply on skin thoroughly, wash and rinse. Suitable for daily use.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients
acrylates copolymer, aloe barbadensis leaf extract, chlorphenesin, cocamidopropyl betaine, disodium EDTA, fragrance, glycerin, glycol distearate, maltodextrin, phenoxyethanol, polyquaternium-7, propylene glycol, purified water usp, shea butter, sodium benzoate, sodium coco-sulfate, sodium laureth sulfate, triethanolamine

Questions or comments? Call 787-740-5317

250 mL NDC : 12961-115-11

FAREWELL COLLECTION

antiseptic shower cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12961-115
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.05 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SHEA BUTTER (UNII: K49155WL9Y)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12961-115-11	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2021	

Labeler - Brisas del Caribe Corp. (090399593)

Establishment

Name	Address	ID/FEI	Business Operations
Paveemol Company Limited		660079138	manufacture(12961-115)

Revised: 12/2022

Brisas del Caribe Corp.