FAREWELL COLLECTION- antiseptic hand soap soap Paveemol Company Limited

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.

Paveemol-Brisas Hand Soap Purple

Active Ingredient(s)

Benzalkonium chloride 0.1%

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.

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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 hands thoroughly, wash and rinse afterward.

Children under 6 years of age should be supervised when using this product.

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, maltodextrin, panthenol, PEG-40 hydrogenated castor oil, phenoxyethanol, PPG-26-Buteth-26, purified water USP, sodium benzoate, sodium hydroxide, sodium lauryl sulfate, tocopheryl acetate

Package Label - Principal Display Panel



250 mL NDC:81892-116-11

FAREWELL COLLECTI antiseptic hand soap soap	ON					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8	31892-116	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Stren	ngth	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)		BENZ ALKONIUM CHLORIDE		0.1 mg in 100 mL		

Ir	nactive Ingi	edients			
Ingredient Name				Strength	
С	HLORPHENESI	(UNII: I670DAL4SZ)			
.A	LPHATOCOP	HEROL ACETATE (UNII: 9E8X80D2L0)			
EC	DETATE DISOD	IUM ANHYDROUS (UNII: 8NLQ36F6MM)			
P/	ANTHENOL (UN	II: WV9CM0067Z)			
M	ALTODEXTRIN	(UNII: 7CVR7L4A2D)			
PC	DLYOXYL 40 H	YDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
A	RYLATES CRO	SSPOLYMER-6 (UNII: 4GXD0Q3OS3)			
SODIUM BENZOATE (UNII: OJ245FE5EU)					
AL	ALOE VERA LEAF (UNII: ZY81Z83H0X)				
PF	PG-26-BUTETH	-26 (UNII: 2II1K6TZ4P)			
GI	LYCERIN (UNII:	PDC6A3C0OX)			
W	ATER (UNII: 059	QF0KO0R)			
С	OCAMIDOPROF	YL BETAINE (UNII: 50CF3011KX)			
Pł	HENOXYETHAN	OL (UNII: HIE492ZZ3T)			
FC	D&C YELLOW I	IO. 5 (UNII: I753WB2F1M)			
FC	D&C BLUE NO.	1 (UNII: H3R47K3TBD)			
SC	DDIUM LAURYL	SULFATE (UNII: 368GB5141J)			
SC	DDIUM HYDRO	KIDE (UNII: 55X04QC32I)			
P	ackaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81892- 116-11	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/23/2021		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	06/20/2021			

Labeler - Paveemol Company Limited (660079138)

Establishment					
Name	Address	ID/FEI	Business Operations		
Paveemol Company Limited		660079138	manufacture(81892-116)		

Revised: 12/2022

Paveemol Company Limited