

AMER FRESH- benzalkonium chloride soap
MRJ'S CROWN INDUSTRIES PRIVATE 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.

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

For washing to decrease bacteria on the skin

Warnings

For external use only.

When using this product avoid contact with eyes .in case of eyes contact ,flush with water

Stop use and doctor ask if irritation and redness develops

Keep out of reach of children if swallowed ,get medical help or contact a Poison control center right away .

Directions

- Wet bar with water
- Lather vigorously and wash skin
- Rinse and dry thoroughly

Inactive ingredients

- Sodium Palmitate
- Palm Kernelate
- Fragrance
- Aqua
- Sodium Chloride
- Glycerine
- Titanium Di Oxide
- Tetra Sodium EDTA

Product label

	 (S-12-AB) - #112 (10GM) AMERFRESH Products, Inc., Woodville, WA 98072. DISTRIBUTED BY : MADE IN INDIA				
					
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; vertical-align: top;"> Drug Facts Active Ingredient Benzalkonium Chloride 0.10%.....Antibacterial Purpose Antibacterial Uses: For washing to decrease bacteria on the skin Warnings: For external use only </td> <td style="width: 33%; vertical-align: top;"> When using this product avoid contact with eyes. in case of eye contact, flush with water Stop use and doctor ask if irritation and redness develops Keep out of reach of children if Swallowed, get medical help or contact a Poison control center right away. </td> <td style="width: 33%; vertical-align: top;"> Drug Facts Directions: • Wet bar with water • Lather vigorously and wash skin • Rinse and dry thoroughly Inactive Ingredients: Sodium Palmate, Palm Kernelate, Fragrance, Aqua, Sodium Chloride, Glycerine, Titanium Di Oxide, Tetra Sodium EDTA </td> </tr> </table>	Drug Facts Active Ingredient Benzalkonium Chloride 0.10%.....Antibacterial Purpose Antibacterial Uses: For washing to decrease bacteria on the skin Warnings: For external use only	When using this product avoid contact with eyes. in case of eye contact, flush with water Stop use and doctor ask if irritation and redness develops Keep out of reach of children if Swallowed, get medical help or contact a Poison control center right away.	Drug Facts Directions: • Wet bar with water • Lather vigorously and wash skin • Rinse and dry thoroughly Inactive Ingredients: Sodium Palmate, Palm Kernelate, Fragrance, Aqua, Sodium Chloride, Glycerine, Titanium Di Oxide, Tetra Sodium EDTA	
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AMER FRESH

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80865-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
SODIUM PALMITATE (UNII: JQ43KP6296)	
PALM KERNEL OIL (UNII: B0S90M0233)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80865-001-01	10 g in 1 POUCH; Type 0: Not a Combination Product	11/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/10/2020	

Labeler - MRJ'S CROWN INDUSTRIES PRIVATE LIMITED (853186269)

Establishment

Name	Address	ID/FEI	Business Operations
MRJ'S CROWN INDUSTRIES PRIVATE LIMITED		853186269	manufacture(80865-001)

Revised: 11/2020

MRJ'S CROWN INDUSTRIES PRIVATE LIMITED