

**AFFEX ANTIBACTERIAL PLUM FOAM HANDWASH- benzalkonium chloride liquid
Afflink, Inc.**

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.

AFFEX® Antibacterial Plum Foam Handwash

Active ingredient

Benzalkonium Chloride 0.5%

Purpose

Antimicrobial

Uses

- Handwash to help decrease bacteria on the skin
- Recommended for repeated use

Warnings

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

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

Directions

- Wet hands
- Apply a small amount of product and work into a lather
- Rinse well and dry hands completely

Inactive Ingredients

Water (Aqua), Propylene Glycol, Glycerin, Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Citric Acid, Ethylhexylglycerin, Lauramine Oxide, Polyquaternium-10, Fragrance (Parfum), Phenoxyethanol, Blue 1 (CI 42090), Red 33 (CI 17200)



Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.5%.....	Antimicrobial
Uses • Handwash to help decrease bacteria on the skin • Recommended for repeated use	
Warnings For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	

Drug Facts (continued)
Directions
• Wet hands • Apply a small amount of product and work into a lather • Rinse well and dry hands completely
Inactive ingredients
Water (Aqua), Propylene Glycol, Glycerin, Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Citric Acid, Ethylhexylglycerin, Lauramine Oxide, Polyquaternium-10, Fragrance (Parfum), Phenoxyethanol, Blue 1 (CI 42090), Red 33 (CI 17200)

Datos Farmacológicos	
Ingrediente activo	Propósito
Cloruro de benzalconio 0,5%	Antimicrobiano
Usos • Lavado de manos empleado para disminuir la cantidad de bacterias en la piel • Recomendado para uso reiterado	
Advertencias Sólo para uso externo	
Al utilizar este producto, evitar el contacto con los ojos o con la zona alrededor de los ojos. En caso de contacto, enjuagar completamente los ojos con agua.	
Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea	
Mantener fuera del alcance de los niños. En caso de ingestión, de inmediato acudir a un médico o ponerse en contacto con un centro para el control de tóxicos.	

Datos Farmacológicos (cont.)	
Modo de uso	
• Mojarse las manos • Aplicar una pequeña cantidad del producto y frotar las manos hasta producir una espuma abundante • Enjuagar bien • Sacarse las manos completamente	
Ingredientes inactivos	
Agua, Propilenglicol, Glicerina, Cocamidopropil betaina, Laurato de PEG-80 sorbitan, Acido cítrico, Ethylhexil Glicerina, Óxido de Lauramina, Poliquaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33	



Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.5%.....	Antimicrobial
Uses • Handwash to help decrease bacteria on the skin • Recommended for repeated use	
Warnings For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	

Drug Facts (continued)
Directions
• Wet hands • Apply a small amount of product and work into a lather • Rinse well and dry hands completely
Inactive ingredients
Water (Aqua), Propylene Glycol, Glycerin, Cocamidopropyl Betaine, PEG-80 Sorbitan Laurate, Citric Acid, Ethylhexylglycerin, Lauramine Oxide, Polyquaternium-10, Fragrance (Parfum), Phenoxyethanol, Blue 1 (CI 42090), Red 33 (CI 17200)

Datos Farmacológicos	
Ingrediente activo	Propósito
Cloruro de benzalconio 0,5%	Antimicrobiano
Usos • Lavado de manos empleado para disminuir la cantidad de bacterias en la piel • Recomendado para uso reiterado	
Advertencias Sólo para uso externo	
Al utilizar este producto, evitar el contacto con los ojos o con la zona alrededor de los ojos. En caso de contacto, enjuagar completamente los ojos con agua.	
Dejar de usar el producto y consultar a un médico si aparece y persiste una irritación o erupción cutánea	
Mantener fuera del alcance de los niños. En caso de ingestión, de inmediato acudir a un médico o ponerse en contacto con un centro para el control de tóxicos.	

Datos Farmacológicos (cont.)	
Modo de uso	
• Mojarse las manos • Aplicar una pequeña cantidad del producto y frotar las manos hasta producir una espuma abundante • Enjuagar bien • Sacarse las manos completamente	
Ingredientes inactivos	
Agua, Propilenglicol, Glicerina, Cocamidopropil betaina, Laurato de PEG-80 sorbitan, Acido cítrico, Ethylhexil Glicerina, Óxido de Lauramina, Poliquaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33	

AFFEX ANTIBACTERIAL PLUM FOAM HANDWASH
benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54057-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.005 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
PEG-80 Sorbitan Laurate (UNII: 239B50Y732)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Lauramine Oxide (UNII: 4F6FC4MI8W)	
POLYQUATERNIUM-10 (10000 MPA.S AT 2%) (UNII: PI1STR9QYH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54057-400-40	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/30/2017	
2	NDC:54057-400-42	1250 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2017	

Labeler - Afflink, Inc. (023121150)