

CLASSIC TOUCH ANTIBACTERIAL PLUM FOAM HANDWASH- benzalkonium chloride liquid

AFFLAB, Affiliated Laboratories, a Division of AFFLINK

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.

CLASSIC TOUCH 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)


CLASSIC TOUCH
 SKIN CARE SOLUTIONS
 Antibacterial Plum
 Foam Handwash
 Jabón espumoso para manos
 antibacterial de ciruelas

Stock No. / Stocker No. /
 Número de Producto:
12561
 Distributed by • Distribuido por:
AFFLAB
 Affiliated Laboratories,
 A Division of/Una división de:
 AFFLINK,
 1400 AFFLINK Place
 Tuscaloosa, AL 35406
 Made in USA, Hecho en los E.E.U.U.

1912-641-ID1

1200 mL (40.5 US/ÉU FL OZ)

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, Etilhexil Glicerina, Óxido de Lauramina, Poliquaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33


CLASSIC TOUCH
 SKIN CARE SOLUTIONS
 Antibacterial Plum
 Foam Handwash
 Jabón espumoso para manos
 antibacterial de ciruelas

Stock No. / Stocker No. /
 Número de Producto:
12561
 Distributed by • Distribuido por:
AFFLAB
 Affiliated Laboratories,
 A Division of/Una división de:
 AFFLINK,
 1400 AFFLINK Place
 Tuscaloosa, AL 35406
 Made in USA, Hecho en los E.E.U.U.

1912-641-ID1

1200 mL (40.5 US/ÉU FL OZ)

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, Etilhexil Glicerina, Óxido de Lauramina, Poliquaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33

CLASSIC TOUCH ANTIBACTERIAL PLUM FOAM HANDWASH
 benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54057-401
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:54057-401-40	1200 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/30/2017	
2	NDC:54057-401-42	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 - AFFLAB, Affiliated Laboratories, a Division of AFFLINK (023121150)