

VICTORIA BAY ANTIBACTERIAL PLUM FOAM HANDWASH- benzalkonium chloride liquid

Dade Paper & Bag, LLC

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.

Victoria Bay 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 | |
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| Datos Farmacológicos | |
|--|------------------------------------|
| Ingrediente activo Cloruro de benzalkonio 0,5% | Propósito 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 • Secarse las manos completamente | |
| Ingredientes inactivos Agua, Propilenglicol, Glicerina, Cocamidopropil betaina, Laurato de PEG-80 sorbitan, Acido cítrico, Etihexil Glicerina, Óxido de lauramina, Policuaternio-10, Fragancia, Fenoxietanol, Azul 1, Rojo 33 | |



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VICTORIA BAY ANTIBACTERIAL PLUM FOAM HANDWASH

benzalkonium chloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71907-400 |
| 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:71907-400-23 | 700 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/30/2017 | |
| 2 | NDC:71907-400-40 | 1200 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/30/2017 | |
| 3 | NDC:71907-400-42 | 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 - Dade Paper & Bag, LLC (004446662)