

BIOCENTRIS E2 HANDWASH- benzalkonium chloride liquid

Inopak, Ltd.

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.

Biocentris E2 Foam Handwash

Active Ingredient

Benzalkonium chloride

Purpose

Antiseptic

Uses

- Handwash to help reduce bacteria on the skin that potentially can cause disease.
- Recommended for repeated use.

Warnings

- For external use only.
- Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes with water.
- Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

When Using

- In case of eye contact, flush eyes with water.

Stoppage

- Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours.

Children

Keep out of reach of children.

Directions

- Dispense a golf ball size amount of foam onto dry hands and rub vigorously for 15 seconds
- Rinse with water and towel dry.

Inactive Ingredients

Cetrimonium chloride, chlorhexidine gluconate, cocamidopropyl PG-dimonium chloride phosphate, decyl glucoside, ethyl alcohol, isopropyl alcohol, phenoxyethanol, polyquaternium 10, polyquaternium 11, water.

E2 single label

<p>E2 FOAM HANDWASH FOR FOOD INDUSTRY PROFESSIONALS One Step Hand Wash & Sanitizer ADVANCED QUAT FORMULA 50 mL Part# BIO-5064-480 888-497-4375 info@biocentris.com www.biocentris.com bi centris PHARMACEUTICALS</p>	<p>Drug Facts</p> <table border="0"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Benzalkonium chloride 0.13% w/w.....</td> <td>Antiseptic</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> • Handwash to help reduce bacteria on the skin that potentially can cause disease. • Recommended for repeated use. <p>Warnings</p> <ul style="list-style-type: none"> • For external use only. • Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes with water. • Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. <p>Directions</p> <ul style="list-style-type: none"> • Dispense a golf ball size amount of foam onto dry hands and rub vigorously for 15 seconds • Rinse with water and towel dry. <p>Inactive Ingredients: Cetrimonium chloride, chlorhexidine gluconate, cocamidopropyl PG-dimonium chloride phosphate, decyl glucoside, ethyl alcohol, isopropyl alcohol, phenoxyethanol, polyquatemium 10, polyquatemium 11, water.</p> <p>Questions? Call 1-888-497-4375</p>	Active Ingredient	Purpose	Benzalkonium chloride 0.13% w/w.....	Antiseptic
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E2 FOAM HANDWASH FOR FOOD INDUSTRY PROFESSIONALS

One Step
Hand Wash
& Sanitizer
ADVANCED
QUAT FORMULA

50mL
Part# BIO-5064-480
888-497-4375
info@biocentris.com
www.biocentris.com



Rev. 1.0

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Questions? Call 1-888-497-4375 or visit biocentris.com

E2 case label

E2 FOAM HANDWASH FOR FOOD
INDUSTRY PROFESSIONALS

One Step Hand Wash
And Sanitizer

ADVANCED QUAT FORMULA

6/1000mL

BIO-5064-CS

888-497-4375

Info@biocentris.com

www.biocentris.com

biocentris

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Rev. 1.0

BIOCENTRIS E2 HANDWASH

benzalkonium chloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58575-402

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium chloride (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	Benzalkonium chloride	0.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-10 (1000 MPA.S AT 2 %) (UNII: GMR4PEN8PK)	
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-402-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2018	
2	NDC:58575-402-02	6000 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2018	

Labeler - Inopak, Ltd. (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak, Ltd.		194718243	manufacture(58575-402)