

**FORTICEPT ANTIMICROBIAL WOUND CLEANSER- benzalkonium chloride liquid
Cosco International, 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.

Drug Facts

Active Ingredient/Purpose

Benzalkonium Chloride.....Antiseptic□

Uses

Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers, cracked skin and lips. Topical antiseptic to help decrease the risk of skin infections.

Warnings For external use only.

Do not use on children under 2 years of age unless directed by a doctor.

When using this product avoid contact with eyes.

Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

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

□**Directions:**

Wound cleansing for adults and children 2 years of age and older:

Spray the affected area to clean dirt and debris, use a small amount of the product and wipe it off with a sterile gauze.

For use as First Aid antiseptic for adults and children 2 years of age and older:

- Clean the affected area
- Spray a small amount of this product on the area 1 to 3 times daily or as needed
- Wipe off excess with sterile gauze
- Cover affected area with a sterile bandage if needed
- When bandaged, let dry first

For children under 2 years of age: please, consult a doctor

□**Storage and handling:**

Store at room temperature.

□**Inactive ingredients:**

chamomile, (matricaria recutita) extract, cocamide MEA, cocamidopropyl betaine, disodium cocamphodiacetate, polyhexanide, water, yarrow (achillea millefolium) extract

60 mL PLPLDP



FORTICEPT™
ANTIMICROBIAL WOUND CLEANSER
 (Benzalkonium Chloride 0.13%)

With natural extracts of
Chamomile & Yarrow

- Fast acting formula
- pH-balanced for gentle & effective cleansing
- Helps reduce risk of infection
 - Supports healing

FOR EXTERNAL USE ONLY

2 fl. oz./60 ml

LIDAN, INC 30 WALL STR. 8th FLOOR NEW YORK, NY 10005 USA WWW.FORTICEPT.COM

FORTICEPT™ ANTIMICROBIAL WOUND CLEANSER

Drug Facts	
Active Ingredient Benzalkonium Chloride (0.13%).....	Purpose Antiseptic
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For questions, please call:
 +1 (212) 709-8133

MADE IN USA



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PATENT PENDING

118 mL PLPLDP



FORTICEPT™
ANTIMICROBIAL WOUND CLEANSER
(Benzalkonium Chloride 0.13%)

With natural extracts of
Chamomile & Yarrow

- Fast acting formula
- pH-balanced for gentle & effective cleansing
- Helps reduce risk of infection
- Supports healing

FOR EXTERNAL USE ONLY
4 fl. oz./118 ml

LIDAN, INC 30 WALL STR. 8th FLOOR NEW YORK, NY 10005 USA WWW.FORTICEPT.COM

FORTICEPT™ ANTIMICROBIAL WOUND CLEANSER

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240 mL PLPLDP



FORTICEPT™
ANTIMICROBIAL WOUND CLEANSER
(Benzalkonium Chloride 0.13%)

With natural extracts of
Chamomile & Yarrow

- Fast acting formula
- pH-balanced for gentle & effective cleansing
- Helps reduce risk of infection
- Supports healing

FOR EXTERNAL USE ONLY
8 fl. oz./240 ml

LIDAN, INC 30 WALL STR. 8th FLOOR NEW YORK, NY 10005 USA WWW.FORTICEPT.COM

FORTICEPT™ ANTIMICROBIAL WOUND CLEANSER

Drug Facts	
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473 ml PLPLDP



FORTICEPT™
ANTIMICROBIAL WOUND CLEANSER
(Benzalkonium Chloride 0.13%)

With natural extracts of
Chamomile & Yarrow

- Fast acting formula
- pH-balanced for gentle & effective cleansing
- Helps reduce risk of infection
- Supports healing

FOR EXTERNAL USE ONLY
 16 fl. oz./473 ml

LIDAN, INC 30 WALL STR. 8th FLOOR NEW YORK, NY 10005 USA WWW.FORTICEPT.COM

FORTICEPT™ ANTIMICROBIAL WOUND CLEANSER

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FORTICEPT ANTIMICROBIAL WOUND CLEANSER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5226 1-0700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
benzalkonium chloride (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6 Y)	benzalkonium chloride	1.3 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
chamomile (UNII: FGL3685T2X)	.1 g in 1000 g
COCO MONOETHANOLAMIDE (UNII: C80684146D)	.5 g in 1000 g
cocamidopropyl betaine (UNII: 5OCF3011KX)	4 g in 1000 g
disodium cocoamphodiacetate (UNII: 18L9G3U51M)	1 g in 1000 g

POLIHAXANIDE (UNII: 322U039GMF)	4 g in 1000 g
water (UNII: 059QF0KO0R)	989.00 g in 1000 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)	.1 g in 1000 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0700-0	60 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/27/2016	
2	NDC:52261-0700-1	118 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/27/2016	
3	NDC:52261-0700-2	240 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/27/2016	
4	NDC:52261-0700-3	473 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/27/2016	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0700) , label(52261-0700) , pack(52261-0700)

Revised: 10/2016

Cosco International, Inc.