FORTICEPT ANTIMICROBIAL GEL- benzethonium chloride gel
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

Benzethonium Chloride.....Antiseptic

Thymol.....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:

Adults and children 2 years of age and older:

Clean affected area from dirt and debris, let it dry. Apply a thin layer of Forticept^{TM} Antimicrobial Gel and cover affected area with a clean bandage if needed. Repeat this procedure 1-3 times daily or as needed until condition improves.

Children under 2 years of age: please, consult a doctor

Storage and handling:

Store at room temperature, avoid freezing

Inactive ingredients:

Allantoin, Blue #1 dye, Cetearyl Alcohol, Chamomile (Matricaria recutita) Extract, Glycerin, Lanolin, Mineral oil, Petrolatum, Polyhexanide, Shea Butter, Simulgel EG, Steareth-2, Steareth-21, Water, Yarrow (Achillea millefolium) Extract

60g PLPLDP

FORTICEPT™

Antimicrobial Gel

(Benzethonium Chloride 0.1% & Thymol 0.063%)

Wound Care & Antiseptic

With natural extracts of

Chamomile & Yarrow

- Fast acting formula
- Moisture Balancing
- Supports healing

FOR EXTERNAL USE ONLY

2 oz./60 g

FORTICEPT™ ANTIMICROBIAL GEL

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Benzethonium Chloride (0.1%)	Antiseptic
Thymol (0.063%)	Antiseptic

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MADE IN USA

LIDAN, INC 30 WALL STR. 8th FLOOR
NEW YORK, NY 10005 USA
WWW.FORTICEPT.COM
For questions, please call:
+1 (212) 709-8133

1 234514 897422

PATENT PENDING

90g PLPLDP

FORTICEPT™

Antimicrobial Gel

(Benzethonium Chloride 0.1% & Thymol 0.063%)

Wound Care & Antiseptic

With natural extracts of

Chamomile & Yarrow

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- Supports healing

FOR EXTERNAL USE ONLY

3 oz./90 g

FORTICEPT™ ANTIMICROBIAL GEL

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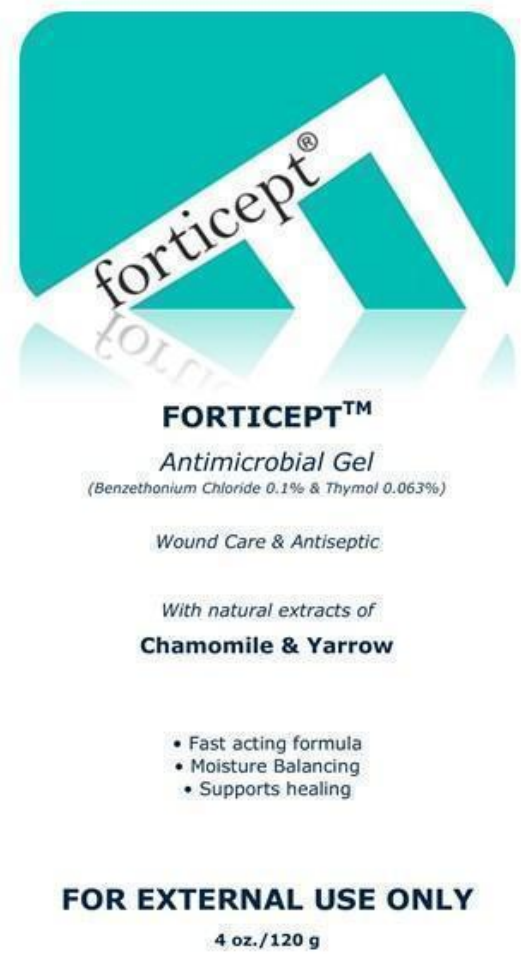
120g PLPLDP



FORTICEPT ANTIMICROBIAL GEL

benzethonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52261-0701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
benzethonium chloride (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	benzethonium chloride	1 g in 1000 g
thymol (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	thymol	1 g in 1000 g

Inactive Ingredients	
Ingredient Name	**Strength**
allantoin (UNII: 344S277G0Z)	2 g in 1000 g
fd&c blue no. 1 (UNII: H3R47K3TBD)	0.009 g in 1000 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	2.8 g in 1000 g

chamomile (UNII: FGL3685T2X)	.1 g in 1000 g
glycerin (UNII: PDC6A3C0OX)	20 g in 1000 g
isohexadecane (UNII: 918X1OUF1E)	3 g in 1000 g
LANOLIN (UNII: 7EV65EAW6H)	1.2 g in 1000 g
mineral oil (UNII: T5L8T28FGP)	1.6 g in 1000 g
petrolatum (UNII: 4T6H12BN9U)	3.6 g in 1000 g
polihexanide (UNII: 322U039GMF)	2 g in 1000 g
polysorbate 80 (UNII: 6OZP39ZG8H)	0.5 g in 1000 g
shea butter (UNII: K49155WL9Y)	.8 g in 1000 g
sodium acrylate/sodium acryloyldimethyltaurate copolymer (4000000 MW) (UNII: 1DXE3F3OZX)	6.5 g in 1000 g
STEARETH-2 (UNII: V56DFE46J5)	1.2 g in 1000 g
STEARETH-21 (UNII: 53J3F32P58)	1.2 g in 1000 g
water (UNII: 059QF0KO0R)	951.591 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:52261-0701-0	60 g in 1 TUBE; Type 0: Not a Combination Product	10/27/2016	
2	NDC:52261-0701-1	90 g in 1 TUBE; Type 0: Not a Combination Product	10/27/2016	
3	NDC:52261-0701-2	120 g in 1 TUBE; 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(52261-0701) , label(52261-0701) , pack(52261-0701)

Revised: 10/2016 Cosco International, Inc.