

**FLORASEPTIC WOUND GEL- benzethonium chloride, allantoin 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.*

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**FloraSeptic Wound Gel - Antimicrobial Skin & Wound Hydrogel**

**DRUG FACTS**

***Active Ingredient/Purpose:***

Benzethonium Chloride (0.12%).....Antiseptic

Allantoin (0.5%).....Skin Protectant

***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 infection

***Warnings:***

**For external use only.**

***Do not use:***

- in the eyes
- over large areas of the body

***Ask a doctor before use if you have:***

- deep or puncture wounds
- deep cuts
- animal bites
- serious burns

***When using this product:***

- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- Apply only to the affected area. Avoid ingestion.

***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 immediately.

***Directions:***

Adults and children 2 years of age and older:

- Clean minor cut, scrapes, or burns by thoroughly flushing the affected area with water or a wound cleanser and let air dry
- Apply appropriate layer of the gel to cover the affected area
- Cover with adhesive bandage or sterile gauze if needed
- Apply 1 to 3 times daily
- Children under 2 years of age: ask a doctor

***Inactive Ingredients:***

Aloe Barbadosis Leaf Juice, C13-14 Isoparaffin, Ethanol, Ethylhexylglycerin, Glycerin, Hydrastis Canadensis L., Hydrolyzed Bovine Collagen, Laureth-7, Panax Quinquefolius L., Phenoxyethanol, Sodium Acryloyldimethyltaurate-Acrylamide Copolymer, Sodium Hyaluronate, Sodium Hydroxide, Water

***Storage and handling:***

Store at room temperature 68°F to 77°F (20° to 25°C)

Do not expose to excessive heat

May discolor or stain certain fabrics

***For Questions:***

**+1-(833) 432-5435**

**BonePharm, LLC.**

6104 River Terrace

Tampa, FL 33604

**1 (833) HEALGEL**

**WWW.BONEPHARM.COM**



## WOUND GEL

(Benzethonium Chloride 0.12% & Allantoin 0.5%)

Antimicrobial Hydrogel  
with  
Hyaluronic Acid & Collagen

- Antimicrobial
- pH Balancing
- Promotes Healing

**FOR EXTERNAL USE ONLY**

BonePharm, LLC

Net Wt. 3 oz. (85g)

### Drug Facts

Active Ingredients:	Purpose
Benzethonium Chloride (0.12%)	Antiseptic
Allantoin (0.5%)	Skin Protectant

### Uses:

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- Topical antiseptic to help decrease the risk of skin infection.

### Warnings:

**For external use only!**

### Do not use:

- in the eyes
  - over large areas of the body
- Ask a doctor before use if you have**
- deep or puncture wounds
  - serious burns
  - deep cuts
  - animal bites

### When using this product

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  - apply only to the affected area. Avoid ingestion.
- 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 immediately.

### Directions:

Adults and children 2 years of age and older:

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- Apply appropriate layer of the gel to cover the affected area
- Cover with adhesive bandage or sterile gauze if needed
- Apply 1 to 3 times daily
- Children under 2 years of age: do not use, consult a doctor

### Inactive ingredients:

Aloe Barbadensis Leaf Juice, C13-14 Isoparaffin, Ethanol, Ethylhexylglycerin, Glycerin, Hydrastis Canadensis L., Hydralized Collagen, Laureth-7, Panax Quinquefolius L., Phenoxyethanol, Sodium Acryloyldimethyltaurate-Acrylamide Copolymer, Sodium Hyaluronate, Sodium Hydroxide, Water

### Other Information:

Store at room temperature 68°F to 77°F (20° to 25°C)  
Do not expose to excessive heat  
May discolor certain fabrics

**For Questions: +1 (833) 432-5435**

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6104 River Terrace  
Tampa, FL 33604  
**1 (833) HEALGEL**  
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Made in USA

## FLORASEPTIC WOUND GEL

benzethonium chloride, allantoin gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52261-0602
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZETHONIUM CHLORIDE</b> (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.0012 kg in 1 kg

ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)

ALLANTOIN

0.0050 kg  
in 1 kg

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 2000-5000 MW) (UNII: 5WE8P977RQ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T)	
LAURETH-7 (UNII: Z95S6G8201)	
PANAX QUINQUEFOLIUS WHOLE (UNII: 0P067WOA1X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0602-1	0.0850 kg in 1 TUBE; Type 0: Not a Combination Product	07/01/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2022	

**Labeler** - Cosco International, Inc. (016433141)

**Registrant** - Cosco International, Inc. (016433141)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0602) , label(52261-0602) , pack(52261-0602)

Revised: 6/2022

Cosco International, Inc.