BERBEREX 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.

BerbereX 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 BerbereX® 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 Barbadensis 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:

Call 1-888-252-6208
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd., Suite G-601
Atlanta, GA 30342
Website: www.berberex.com

BerberexX®

Wound Gel

(Benzethonium Chloride 0.12% & Allantoin 0.5%)

Antimicrobial Hydrogel with Hyaluronic Acid & Collagen

- pH Balanced
- Antimicrobial
- Promotes Healing

FOR EXTERNAL USE ONLY

NuVision Pharmaceuticals

Net Wt. 3 oz. (85g)

Drug Facts

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

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

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- Cover with adhesive bandage or sterile gauze if needed
- Apply 1 to 3 times daily
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Inactive ingredients:

Aloe Barbadensis Leaf Juice, Alpha-1 Type I Collagen, C11-14 Isoparaffin, Ethanol, Ethylhexylglycerin, Glycerin, Hydrastis Canadensis L., 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 (888) 252-6208

NUVISION PHARMACEUTICALS, LLC.
4651 ROSWELL RD., SUITE G-601 ATLANTA, GA 30342
WWW.BERBEREX.COM

Made in USA

BERBEREX WOUND GEL

benzethonium chloride, allantoin gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52261-0601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZETHONIUM CHLORIDE (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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0601-1	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(52261-0601) , label(52261-0601) , pack(52261-0601)

Revised: 6/2022 Cosco International, Inc.