BERBEREX WOUND CLEANSER- benzethonium 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

Allantoin 0.5%.....Skin Protectant

Benzethonium 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

- in large quantities, particularly over raw surfaces or blistered areas

Ask doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask doctor if

- condition worsens
- symptons persist for 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:

- use to clean minor cut, scrapes, and burns by thoroughly flushing the affected area
- let air dry
- cover with adhesive bandage or sterile gauze
- apply a small amount of this product on the area 1 to 3 times daily

Children under 2 years of age: do not use, consult a doctor

Inactive ingredients:

Aloe barbadensis Mill, Ethanol, Hydrastis canadensis L., Hydrogen Peroxide, Panax quinquefolis L., Water

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

NuVision Pharmaceuticals

Net Wt. 4 Fl. Oz. / 118 mL

0 799475 062124

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	Purpose
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive Ingredients Water, Ethanol, Aloe barbadensis Mill., Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide.

Made in USA

2424005

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

NuVision Pharmaceuticals

Net Wt. 4 Fl. Oz. / 118 mL

0 799475 062124

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	Purpose
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive Ingredients Water, Ethanol, Aloe barbadensis Mill., Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide.

Made in USA

2424005

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

NuVision Pharmaceuticals

Net Wt. 4 Fl. Oz. / 118 mL

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

0 799475 062124

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	*Purpose*
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive Ingredients Water, Ethanol, Aloe barbadensis Mill., Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide.

Made in USA

2424005

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

NuVision Pharmaceuticals

Net Wt. 8 Fl. Oz. / 237 mL

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	Purpose
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive ingredients Water, Ethanol, Aloe barbadensis Mill, Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide

Made in USA

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

0 799475 062131

2424006

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

NuVision Pharmaceuticals

Net Wt. 8 Fl. Oz. / 237 mL

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	Purpose
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive ingredients Water, Ethanol, Aloe barbadensis Mill, Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide

Made in USA

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

0 799475 062131

2424006

BerbereX®
WOUND CLEANSER

BerbereX®
WOUND
CLEANSER

FOR EXTERNAL USE ONLY

- Antimicrobial
- pH Balancing
- Promotes Healing

NuVision Pharmaceuticals

Net Wt. 8 Fl. Oz. / 237 mL

BerbereX®
WOUND CLEANSER

CONSULT YOUR DOCTOR BEFORE USE

Drug Facts

Active Ingredient	Purpose
Allantoin 0.5%	Skin Protectant
Benzethonium Chloride 0.1%	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 ■ in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns

Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for 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:
■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze ■ apply a small amount of this product on the area 1 to 3 times daily
Children under 2 years of age: do not use, consult a doctor

Inactive ingredients Water, Ethanol, Aloe barbadensis Mill, Hydrastis canadensis L., Panax quinquefolis L., Hydrogen Peroxide

Made in USA

Manufactured for:
NuVision Pharmaceuticals, LLC.
4651 Roswell Rd. Suite G-601
Atlanta, GA 30342
www.berberex.com

0 799475 062131

2424006

BERBEREX WOUND CLEANSER

benzethonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52261-0500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 g in 1000 mL
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T)	
PANAX QUINQUEFOLIUS WHOLE (UNII: 0P067WOA1X)	
hydrogen peroxide (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0500-1	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/24/2015	
2	NDC:52261-0500-2	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/24/2015	
3	NDC:52261-0500-3	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/24/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/17/2015	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0500) , label(52261-0500) , pack(52261-0500)

Revised: 1/2020 Cosco International, Inc.