

FORTICEPT WOUNDS AND BURNS HYDROGEL- benzethonium chloride, lidocaine hydrochloride gel

Lidan, 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.

Forticept Wounds and Burns Hydrogel

DRUG FACTS

Active Ingredient/Purpose:

LIDOCAINE HCL (4.0%).....Topical Analgesic
BENZETHONIUM CHLORIDE (0.1%).....Antiseptic

Uses:

For temporary relief of pain or discomfort for superficial and full thickness burns or wounds. Topical antiseptic to help decrease the risk of infections. Helps protect skin and supports healing of cuts, scrapes, burns, and wounds.

Topical analgesic - for temporary relief of pain or discomfort for superficial and full thickness burns or wounds.

Topical antiseptic - to help decrease the risk of wound and skin infections.

WARNINGS:

For external use only!

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

When using this product avoid contact with eyes.

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

Discontinue Use after 7 days unless directed by a doctor

Directions:

Adults and children 2 years of age and older:

- Clean affected area from dirt and debris, let it dry.
- Apply Forticept Analgesic Antiseptic Hydrogel and cover affected area with a clean gauze if needed.
- Repeat this procedure 1-3 times daily or as needed until condition improves or medical assistance is rendered.

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

Inactive Ingredients:

ALLANTOIN, ALPHA TOCOPHEROL, C13-14 ISOPARAFFIN, CETOSTEARYL ALCOHOL, CHLORPHENESIN, D-PANTHENOL, FD&C BLUE #1, GLYCERIN, HYDROLYZED COLLAGEN, LANOLIN, LAURETH-7, PARAFFINUM LIQUIDUM, PETROLATUM, POLYACRYLAMIDE, POLYHEXANIDE, SHEA BUTTER, STEARETH-2, STEARETH-21,

THYMOL, WATER

Storage and handling:

- Keep container closed when not in use.
- Store at room temperature, avoid freezing.
- Do not store below 32F/0°C or above 95F/35°C for extended periods of time.

For Questions:

Lidan, Inc.
30 Wall Street, 8th Floor
New York, NY 10005
www.forticept.com

Please call: +1 212 709-8133



Wounds & Burns Analgesic Antiseptic Hydrogel

(Lidocaine HCl 4.0% & Benzethonium Chloride 0.1%)



Advanced Polymer Technology

- Instant Pain Relief
- Infection Control
- Healing Support

FOR EXTERNAL USE ONLY
4 oz./114 g

Forticept® Analgesic Antiseptic Hydrogel

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Benzethonium Chloride (0.1%).....	Antiseptic
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Directions	
For adults and children 2 years of age and older: Clean affected area from dirt and debris, let it dry. Apply Forticept® Analgesic Antiseptic Hydrogel and cover affected area with a clean gauze if needed. Repeat this procedure 1-3 times daily or as needed until condition improves or medical assistance is rendered. For children under 2 years of age: please, consult a doctor	
Storage & Handling: store at room temperature, avoid freezing	
Inactive Ingredients: Allantoin, Alpha Tocopherol, C13-14 Isoparaffin, Cetostearyl Alcohol, Chlorphenesin, D-Panthenol, FD&C Blue #1, Glycerin, Hydrolyzed Collagen, Lanolin, Laureth-7, Mineral Oil, Petrolatum, Polyacrylamide, Polyhexanide, Shea Butter, Steareth-2, Steareth-21, Thymol, Water	



MADE IN USA

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For questions, please call:
+1 (212) 709-8133



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FORTICEPT WOUNDS AND BURNS HYDROGEL

benzethonium chloride, lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72127-0803
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.001 kg in 1 kg
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 kg in 1 kg

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 2000-5000 MW) (UNII: 5WE8P977RQ)	
LANOLIN (UNII: 7EV65EAW6H)	
LAURETH-7 (UNII: Z95S6G8201)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POLIHEXANIDE (UNII: 322U039GMF)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
THYMOL (UNII: 3J50XA376E)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72127-0803-0	0.114 kg in 1 TUBE; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/06/2020	

Labeler - Lidan, inc. (014456716)

Registrant - Lidan, inc. (014456716)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(72127-0803) , relabel(72127-0803) , pack(72127-0803)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmex Group, LLC.		365309015	manufacture(72127-0803) , relabel(72127-0803) , pack(72127-0803) , repack(72127-0803)

Revised: 5/2020

Lidan, inc.