# CURX ANTIMICROBIAL GEL - benzalkonium chloride gel Global Health Solutions, LLC

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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### **DRUG FACTS**

### **Active Ingredients**

Benzalkonium Ch. 0.13% (i/s\*)

### Purpose

First Aid Antiseptic

### Uses

first aid to to help treat, protect and prevent skin infection associated with

- minor cuts
- scrapes
- burns

### **Warnings**

For external use only

### Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

### When using this product

- Do not use in or near the eyes
- do not use if you have a history of allergy to any of the ingredients.

### 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 right away.

### **Directions**

• adults and children 2 years and older: clean the affected area; apply a small amount on the area 1-3 times daily;may be covered with a sterile bandage (let dry first)

• children under 2 years: ask a doctor

### **Other Information**

Avoid excessive heat

## **Inactive Ingredients**

USP Petrolatum, Water, Polihexanide (PHMB)

## Questions?

1-706-844-1025

## **Principal Display Panel**

GLOBAL HEALTH SOLUTIONS, LLC

CurXTM Antimicrobial Gel

First Aid Antimicrobial Gel

Hospital and Professional Use Only

Non-Antibiotic

5 g

CurX is a registered trademark of Global Health Solutions

CurX<sup>TM</sup>
Antimicrobial Gel
Hospital and Professional Use Only
Non Antibiotic
5g

CurX ™
Antimicrobial C
Non Antibiotic
5g

Hospital and Professional Use Only

Manufactured By: Global Health Solutions, LLC Wilmington, DE 19808 706-844-1025 CurXTM
Antimicrobial
Gel
First Aid
Antimicrobial Gel
Hospital and Professional Use Only
Non Antibiotic
5g

CurX is a registered trademark of
Global Health Solutions

CurX MANTIMIC Cobial Gel

Manufactured By Global Health Solutions, LLC Rome, GA 30165 706-844-1025 Hospital and Professional Use Only

DRUG FACTS Active Ingredients Purpose Benzalkonium Ch. 0.13% (i/s\* Uses first aid to help treat, protect, and prevent skin infection associated with minor cuts Warnings For external use only. Ask a doctor before use if you have ● deep or puncture wounds ● animal bites ● serious burns When using this product 

Do not use in or near the eyes 

do not use if you have a history of allergy to any of the ingredients Stop use and ask a doctor if o 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 medica help or contact a Poison Control Center right away Directions • adults and children 2 years and older: clean the affected area; apply a small amount on the area 1-3 times daily; may be covered with a sterile 69578-466-05 bandage (let dry first) . children Other Information Avoid excessive heat Inactive Ingredients USP Petrolatum, Water Polihexanide (PHMB) Questions? (706)844-1025 Percentage reflective of bioavailable/delivered activing redient to affected area(s).

# \*Microdroplet Suspension Technology

\*Proprietary microdroplet suspension technology. Percentage reflective of active ingredient bioavailability in solution.

# CURX ANTIMICROBIAL GEL benzalkonium chloride gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - | BENZALKONIUM      | 0.13 g   |
| UNII:7N6JUD5X6Y)   | CHLORIDE          | in 100 g |

| Inactive Ingredients            |          |  |
|---------------------------------|----------|--|
| Ingredient Name                 | Strength |  |
| WATER (UNII: 059QF0KO0R)        |          |  |
| PETROLATUM (UNII: 4T6H12BN9U)   |          |  |
| POLIHEXANIDE (UNII: 322U039GMF) |          |  |

| Packaging          |  |                             |                    |
|--------------------|--|-----------------------------|--------------------|
| # Item Code        | Package Description                              | <b>Marketing Start Date</b> | Marketing End Date |
| 1 NDC:69578-466-05 | 5 g in 1 TUBE; Type 0: Not a Combination Product |                             |                    |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333A                                 | 10/28/2015           |                    |  |
|                         |  |                      |                    |  |

# **Labeler -** Global Health Solutions, LLC (079695890)

| Establishment                |         |           |                        |  |  |
|------------------------------|---------|-----------|------------------------|--|--|
| Name                         | Address | ID/FEI    | Business Operations    |  |  |
| Global Health Solutions, LLC |         | 079695890 | manufacture(69578-466) |  |  |

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