**CVS PHARMACY - benzalkonium chloride, pramoxine hydrochloride spray**
**Health-Tech, 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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**Drug Facts**

**Active Ingredients**

Benzalkonium Chloride

Pramoxine Hydrochloride

**Purpose**

First Aid Antispetic

Topical Analgesic

**Uses**

First aid to help prevent infection and temporarily relieve pain or discomfort in minor cuts, scrapes and burns.

**Warnings**
**For external use only.**

**Do not use**
Do not use
- in the eyes
- overlarge areas of the body

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

**Stop use and ask a doctor if:**
- condition or symptoms get worse or last more than one week
- symptoms 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 of age and older:
- clean the affected area
- spray a small amount of this product on the area 1 to 3 times daily

- may be covered with a sterile bandage
- if bandaged, let dry first

Children under 2 years of age: consult a doctor

**Other information**

Store at $20^0$ to $25^0$ C ($68^0$ to $77^0$ F) Prior to initial use, prime pump by depressing multiple times.

**Inactive Ingredients:**

DI Water, Edetate Disodium, Propylene Glycol

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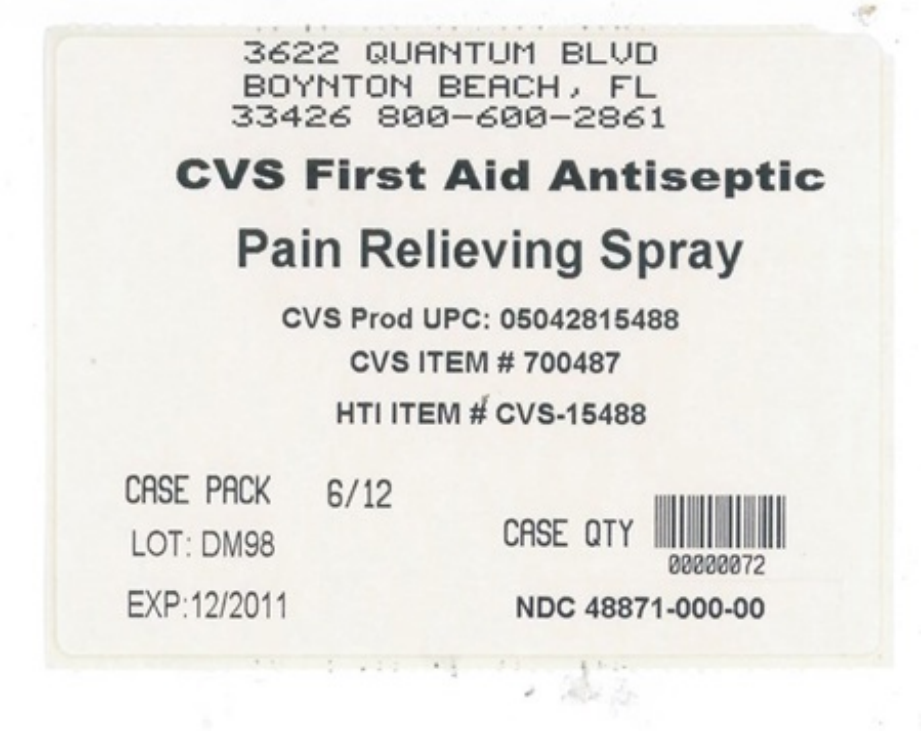


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# CVS PHARMACY

benzalkonium chloride, pramoxine hydrochloride spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:48871-000 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Benzalkonium Chloride** (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y) | Benzalkonium Chloride | .195 mL in 15 mL |
| **Pramoxine Hydrochloride** (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056) | Pramoxine Hydrochloride | .15 mL in 15 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **Edetate Disodium** (UNII: 7FLD91C86K) | |
| **Propylene Glycol** (UNII: 6DC9Q167V3) | |
| **Water** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:48871-000-00 | 12 in 1 BOX | | |
| **1** | | 6 in 1 CARTON | | |
| **1** | | 1 in 1 BLISTER PACK | | |
| **1** | | 15 mL in 1 BOTTLE, SPRAY | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part310.545 | 01/19/2010 | |

## Labeler - Health-Tech, Inc. (084007889)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Health-Tech, Inc. | | 084007889 | manufacture |

Revised: 1/2010 Health-Tech, Inc.