# PROSTAT ANTISEPTIC FIRST AID- benzocaine and benzethonium chloride aerosol, spray ProStat First Aid

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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## **ProStat Antiseptic Spray**

## **Active Ingredients**

Benzethonium Chloride 0.2% w/w Benzocaine 10% w/w

### **Purpose**

Topical antiseptic Topical anesthetic

#### Uses

Treatment of minor cuts and abrasions Pain relief Helps prevent infection Soothes itching

## Warnings

#### **IFor external use only**

#### **Flammable**

Keep away from fire or flame Contents under pressure Do not puncture or incinerate container Do not expose to temperatures above 120° F

#### Do not use

In or eyes or near mucous membranes For serious burns Deep puncture wounds For a prolonged period of time

## Stop use and ask a doctor if

Irritation, redness, or swelling increases Rash or infection occurs Condition worsens or symptoms persist for more than 7 days.

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

#### **Directions**

Hold 4-6 inches from surface Spray area until wet Clean the affected area Shake can well before using For adult institutional use only Not intended for use on children

#### Other information

Avoid inhaling
Use only as directed
Intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal

### **Inactive ingredients**

dipropylene glycol, isobutane, n-butane, propane

### **Principal Display**



#### PROSTAT ANTISEPTIC FIRST AID

benzocaine and benzethonium chloride aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-0104(NDC:52982-100)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZETHO NIUM CHLO RIDE</b> (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	170 mg in 85 g	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII:U3RS Y48 JW5)	BENZOCAINE	8500 mg in 85 g	

Inactive Ingredients		
Ingredient Name	Strength	
DIPROPYLENE GLYCOL (UNII: E107L85C40)		
ISOBUTANE (UNII: BXR49TP611)		
BUTANE (UNII: 6LV4FOR43R)		
PROPANE (UNII: T75W9911L6)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58228-0104-3	85 g in 1 BOTTLE, SPRAY		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/18/2014	

## Labeler - ProStat First Aid (061263699)

## Registrant - Dixon Investments, Inc. (115315822)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dixon Investments, Inc.		115315822	manufacture (58228-0104)	

Revised: 3/2014 ProStat First Aid