

PROSTAT PROTECTIVE COATING BANDAGE FIRST AID- benzethonium chloride and benzocaine 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.

ProStat Bandage Spray

Active ingredients

Benzethonium Chloride 0.2% w/w

Benzocaine 3.2% w/w

Purpose

Topical antiseptic

Topical anesthetic

Uses

☐ **First aid to help protect against infection in**

☐ minor cuts

scrapes

burns

Warnings

☐ **For 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 near eyes or other mucous membranes

in case of serious burns

in deep puncture wounds

for a prolonged period of time

on large portions of the body

Stop use and ask a doctor if

redness, swelling, or irritation occurs

infection occurs

condition persists or worsens

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

clean the affected area
shake can well before using
hold 4-6 inches from surface and spray area until wet
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 contents may be harmful or fatal

Inactive ingredients

Ethyl alcohol, PVP-VA copolymer, N-Butane, Propane, Isobutane

Principal Display

PROSTAT FIRST AID

Protective Coating Bandage Spray

- Provides a protective coating for minor burns, cuts, skin irritation, and minor insect bites
- Water soluble

Aerosol
WARNING: FLAMMABLE
CONTENTS UNDER PRESSURE, READ BACK PANEL CAREFULLY
NET WEIGHT 3 OZ (85G)

Manufactured for
ProStat First Aid LLC
Valencia, CA, 91355
prostatfa.com

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Drug Facts	
Active Ingredients	Purpose
Benzethonium Chloride 0.2% w/w	Topical Antiseptic
Benzocaine 3.2% w/w	Topical Anesthetic
Uses First Aid to help protect against infection in: ■ minor cuts ■ scrapes ■ burns	
Warnings For external use only	
Flammable ■ Keep away from fire or flame ■ Do not puncture or incinerate container ■ Contents under pressure ■ Do not expose to temperatures above 120° F	
Do not use ■ in or near eyes or other mucous membranes ■ in case of serious burns ■ in deep puncture wounds ■ for a prolonged period of time ■ on large portions of the body	
Stop use and ask a doctor if ■ redness, swelling, or irritation occurs ■ infection occurs ■ condition persists or worsens ■ 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 ■ clean the affected area ■ shake can well before using ■ hold 4-6 inches from surface and spray area until wet ■ 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 Ethyl Alcohol, PVP-VA Copolymer, N-Butane, Propane, Isobutane	

PROSTAT PROTECTIVE COATING BANDAGE FIRST AID

benzethonium chloride and benzocaine aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-0102(NDC:52982-105)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)		BENZETHONIUM CHLORIDE	170 mg in 85 g	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	2720 mg in 85 g	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
ISOBUTANE (UNII: BXR49TP611)				
BUTANE (UNII: 6LV4FOR43R)				
PROPANE (UNII: T75W9911L6)				
COPOVIDONE K25-31 (UNII: D9C330MD8B)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-0102-3	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	part333A	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(58228-0102)

Revised: 2/2014

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