PROSTAT BURN FIRST AID- benzethonium chloride, benzocaine, and menthol 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 Pain Relieving Burn Spray

Active Ingredients

Benzocaine 10% w/w Benzethonium Chloride .2% w/w Menthol .33% w/w

Purpose

Topical Antiseptic Topical Antiseptic Topical Anesthetic

Uses

IFor temporary relief of pain, itching and to help protect against infection in

minor cuts and scrapes burns sunburns insect bites minor skin irritations

Warnings

IFor external use only

IFlammable

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 prolonged period of time on large portions of the body

Stop use and ask a doctor if

redness, swelling, or irritation occurs infection occurs conditions worsen or symptoms persist for more than 7 days

IKeep 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 spraying in eyes 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 BURN FIRST AID

benzethonium chloride, benzocaine, and menthol aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-0105(NDC:52982-101)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHO NIUM CHLO RIDE (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	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	281 mg in 85 g	

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-0105-3	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(58228-0105)	

Revised: 3/2014 ProStat First Aid