PROSTAT BLOOD CLOTTING FIRST AID- benzethonium chloride and lidocaine 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 Blood Clotting Spray

Active Ingredients

Benzethonium Chloride 0.2% w/w Lidocaine 4% w/w

Purpose

Topical antiseptic Topical anesthetic

Uses

for help in control of superficial bleeding for temporary relief of pain and to help protect against infection in: minor cuts scrapes burns

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 eyes or other mucous membranes on large portions of the body in case of deep or puncture wounds on raw surfaces on blistered areas on animal bites on serious burns

Stop use and ask a doctor if

redness, swelling, or irritation occurs infection occurs condition persists or worsens

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

Directions

shake can well before using hold 6-8 inches from moist injured area spray until area is covered scab-like cover will gradually disappear as healing takes place or may be removed with soap and water for adult institutional use only not intended for use on children

Inactive ingredients

isobutane, isopropyl myristate, karaya, n-butane, propane, silica, silicone, sorbitan monooloate, talc, tragacanth.

Principal Display



PROSTAT BLOOD CLOTTING FIRST AID benzethonium chloride and lidocaine aerosol, spray

Prod	uct	Info	rmat	ion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58228-0103(NDC:52982-106)

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	3400 mg in 85 g		
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	170 mg in 85 g		

Inactive Ingredients			
Ingredient Name	Strength		
ISOBUTANE (UNII: BXR49TP611)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			
KARAYA GUM (UNII: 73W9 IQY50 Q)			
BUTANE (UNII: 6LV4FOR43R)			
PROPANE (UNII: T75W9911L6)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SORBITAN MONOOLEATE (UNII: 06 XEA2 VD56)			
TALC (UNII: 7SEV7J4R1U)			
TRAGACANTH (UNII: 2944357O2O)			

Packag	ing			
# 1	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58	3228-0103-3	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(58228-0103)		

Revised: 3/2014 ProStat First Aid