AEROBURN BURN FIRST AID- benzethonium chloride, benzocaine, and menthol aerosol, spray

Aero Healthcare, LLC.

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.

AEROBURN BURN SPRAY

Active Ingredients

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

Purpose

Topical Anesthetic Topical Antiseptic Topical Anesthetic

Uses

For temporary relief of pain, treatment and helps prevent infection in

- minor cuts and scrapes
- insect bites
- minor skin irritations
- burns
- sunburns

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 mucous membranes
- on serious burns
- on deep puncture wounds
- for prolonged period of time
- on a large portion 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

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
- for adult institutional use only
- hold 4-6 inches from surface and spray area until wet
- not for use on children
- may be covered with a sertile bandage. If bandaged, let dry first.

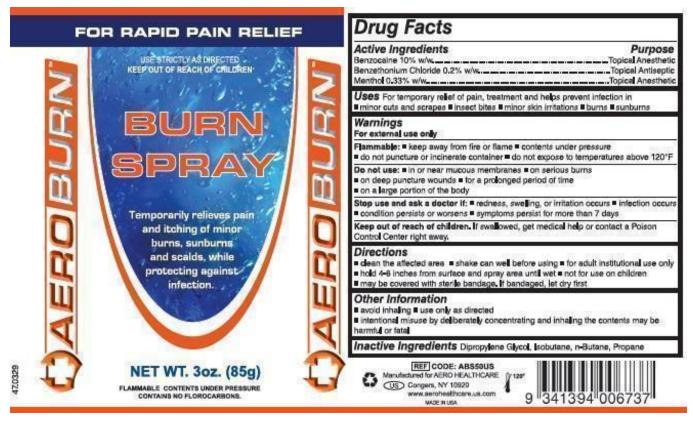
Other information

- 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



benzethonium chloride, benzocaine, and menthol aerosol, spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-116(NDC:52982-101)	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHO NIUM - 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)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55305-116-10	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	08/20/2014		

Labeler - Aero Healthcare, LLC. (008186174)

Registrant - Dixon Investments, Inc. (115315822)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dixon Investments, Inc.		115315822	manufacture(55305-116)	

Revised: 9/2014 Aero Healthcare, LLC.