

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

☐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 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

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
- 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 sterile 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

The image shows the principal display panel for AEROBURN BURN SPRAY. The packaging is blue and white with orange accents. The top of the panel reads "FOR RAPID PAIN RELIEF". Below this, it says "USE STRICTLY AS DIRECTED" and "KEEP OUT OF REACH OF CHILDREN". The product name "AEROBURN BURN SPRAY" is prominently displayed in large, bold letters. Below the name, it states "Temporarily relieves pain and itching of minor burns, sunburns and scalds, while protecting against infection." At the bottom of the panel, it indicates "NET WT. 3oz. (85g)" and "FLAMMABLE. CONTENTS UNDER PRESSURE. CONTAINS NO FLUOROCARBONS." To the right of the packaging is a "Drug Facts" label. The label includes sections for "Active Ingredients" (Benzocaine 10% w/w, Benzethonium Chloride 0.2% w/w, Menthol 0.33% w/w), "Purpose" (Topical Anesthetic, Topical Antiseptic), "Uses" (For temporary relief of pain, treatment and helps prevent infection in minor cuts and scrapes, insect bites, minor skin irritations, burns, sunburns), "Warnings" (For external use only; 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 on or near mucous membranes, on serious burns, on deep puncture wounds, for a prolonged period of time, or on a large portion of the body), "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 sterile 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), and "Inactive Ingredients" (Dipropylene Glycol, Isobutane, n-Butane, Propane). The label also includes a "REF" code (AB550US), manufacturer information (AERO HEALTHCARE, Congers, NY 10920), a barcode (9 341394 006737), and "MADE IN USA".

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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
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	170 mg in 85 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	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 mono graph 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.