

**YOUR LOGO HERE BURN FIRST AID- benzocaine, benzethonium chloride, and menthol aerosol, spray
Dixon Investments, Inc.**

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.

YOUR LOGO HERE BURN SPRAY

Active Ingredients

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

Purpose

Topical Anesthetic
Topical Anesthetic
Topical Anesthetic

Uses

For temporary relief of pain and itching and help protect against infection in
minor cuts and scrapes
burns
sunburns insect bites minor skin irritations

Warnings

For external use only

Flammable

keep away from fire or flame

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

When using this product

avoid spraying in eyes
contents under pressure do not puncture or incinerate container do not store at temperatures above 120°(F) use only as directed intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal

Stop use and ask doctor if

redness, swelling, or irritation occurs

infection occurs
 conditions worsens or 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

Inactive Ingredient

Dipropylene glycol, isobutane, n-butane, and propane

Principal Display



Drug Facts	
Active Ingredients	Purpose
Benzocaine 10%w/w.....	Topical Anesthetic
Benzethonium Chloride 0.2%w/w.....	Topical Anesthetic
Menthol .33% w/w.....	Topical Anesthetic
Uses For temporary relief of pain and itching and help protect against infection in	•burns •sunburns
•insect bites	•minor skin irritations
Warnings	
For external use only	
Flammable	•keep away from fire or flame
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
When using this product	•avoid spraying in eyes
•content is under pressure	•do not puncture or incinerate container
•do not store at temperatures above 120 °F	•use only as directed
•intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal	
Stop use and ask doctor if	•redness, swelling, or irritation occurs
•infection occurs	•condition worsens or 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
•hold 4-6 inches from surface and spray area until wet	•shake can well before using
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Inactive Ingredient	Dipropylene glycol, isobutane, n-butane, and propane

Manufactured for:

YOUR LOGO HERE BURN FIRST AID

benzocaine, benzethonium chloride, and menthol aerosol, spray

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	8500 mg in 85 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	170 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:52982-101-03	85 g in 1 BOTTLE, SPRAY		
2	NDC:52982-101-01	14.2 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	04/05/2013	

Labeler - Dixon Investments, Inc. (115315822)**Registrant** - Dixon Investments, Inc. (115315822)**Establishment**

Name	Address	ID/FEI	Business Operations
Dixon Investments, Inc.		115315822	manufacture(52982-101)

Revised: 5/2013

Dixon Investments, Inc.