

**YOUR LOGO HERE BURN FIRST AID- benzalkonium chloride and benzocaine spray,
metered**

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 WITH ALOE VERA

☐Active Ingredients

Benzalkonium Chloride 0.14%

Benzocaine 5.0%

Purpose

Topical Antiseptic

Topical Anesthetic

Uses

Treatment of minor cuts

Pain relief

Helps prevent infection

Warnings

For external use only

Do not use

in eyes or near mucous membranes

For serious burns

For prolonged period of time

Stop use and ask a doctor if

Irritation, redness, or swelling increases

Rash or infection occurs

☐Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center right away

Directions

Hold 4-6 inches from surface

Spray area until wet

Inactive Ingredients

Aloe Vera Gel, Isopropyl Alcohol, Menthol, Propylene Glycol, Water

Principal Display

BURN SPRAY

With Aloe Vera

Indications:

- Treats minor burns
- Relieves pain
- Helps prevent infections
- Washable

3 fl. Oz. (90 ml)

Drug Facts	
Active Ingredients	Purpose
Benzalkonium Chloride 0.14%.....	Topical Antiseptic
Benzocaine 5.0%.....	Topical Anesthetic
Uses	
<ul style="list-style-type: none"> • Treatment of minor cuts • Pain relief • Helps prevent infection 	
Warnings	
For external use only	
<i>Do not use</i> • in eyes or near mucous membranes	
• For serious burns • For prolonged period of time	
<i>Stop use and ask a doctor if</i>	
• Irritation, redness, or swelling increases	
• Rash or infection occurs	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away	
Directions	
• Hold 4-6 inches from surface	
• Spray area until wet	
Inactive Ingredients	
• Aloe Vera Gel, Isopropyl Alcohol, Menthol	
• Propylene Glycol, Water	

Distributed by:

48.0005

YOUR LOGO HERE BURN FIRST AID

benzalkonium chloride and benzocaine spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52982-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	3825 mg in 90 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	107.1 mg in 90 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52982-121-13	90 mL in 1 BOTTLE, SPRAY		
2	NDC:52982-121-12	59 mL 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(52982-121)

Revised: 4/2013

Dixon Investments, Inc.