

YOUR LOGO HERE POISON IVY FIRST AID- benzethonium chloride and benzocaine 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 POISON IVY RELIEF

☐Active Ingredients

Benzethonium Chloride 0.15% w/w

Benzocaine 5.0% w/w

Purpose

Topical Antiseptic

Topical Anesthetic

Uses

For temporary relief of pain and itching and to help protect against infection in minor skin irritations

rashes due to poison ivy, poison sumac and insect bites

Warnings

☐For external use only

Extremely 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 the eyes or other mucous membranes

in case of serious burn

in deep puncture wounds

for a prolonged period of time

on large portions 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
 hold can 4 to 6 inches away from injury and spray area until wet
 for adult institutional use only
 not intended for children

Other Information

avoid inhaling
 use only as directed
 intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal

Inactive Ingredients

Isopropyl Myristate, PVP-VA, SDA-40-200 Alcohol, N-Butane, Propane, Isobutane

Principal Display

YOUR LABEL HERE

**POISON
 IVY**

- Water Soluble
- Protects cuts and abrasions
- Helps prevent infection

FLAMMABLE
 Contents Under Pressure

Contains no Fluorocarbons
 NET WT. 3 oz. (85g)

Drug Facts
Active Ingredients Benzethonium Chloride 0.15% w/w Benzocaine 5.0% w/w
Purpose Topical Antiseptic Topical Anesthetic
Uses For temporary relief of pain and itching and to help protect against infection in <ul style="list-style-type: none"> • minor skin irritations • rashes due to poison ivy, poison sumac and insect bites
Warnings For external use only
Extremely Flammable <ul style="list-style-type: none"> • keep away from fire or flame • contents under pressure • do no puncture or incinerate container • do not expose to temperatures above 120 degrees F
Do not use <ul style="list-style-type: none"> • in or near the eyes or other mucous membranes • in case of serious burn • in deep puncture wounds • for a prolonged period of time • on large portions of the body
Stop use and ask a doctor <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • clean the affected area • shake can well before using • hold can 4 to 6 inches away from injury and spray area until wet • for adult institutional use only • not intended for use on children
Other Information <ul style="list-style-type: none"> • avoid inhaling • use only as directed intentional misuse by deliberately concentrating and inhaling the contents may be harmful or fatal
Inactive Ingredients Isopropyl Myristate, PVP-VA, SDA-40-200 Alcohol, N-Butane, Propane, Isobutane

Manufactured for: Your Company Here

YOUR LOGO HERE POISON IVY FIRST AID

benzethonium chloride and benzocaine aerosol, spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:52982-107

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	4250 mg in 85 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	127.5 mg in 85 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PVP/VA COPOLYMER (UNII: D9C330MD8B)	
ALCOHOL (UNII: 3K9958V90M)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
ISOBUTANE (UNII: BXR49TP611)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52982-107-03	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	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(52982-107)

Revised: 4/2013

Dixon Investments, Inc.