

FIRST DEGREE BURN- benzocaine, triclosan spray
The Akshay Wellness Group, 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.

First°Degree® Burn Spray

Active ingredients

Benzocaine 20.0%

Triclosan 0.13%

Purpose

Pain relieving spray

First aid antiseptic

Uses

- for temporary relief of pain and itching from minor burns, cuts and scrapes
- first aid to help prevent infection in minor burns, cuts and scrapes

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame.

Do not use

- in the eyes
- over large areas of the body

When using this product

- keep out of eyes
- use only as directed
- do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F.

Ask a Physician before use if you have

- serious burns
- deep or puncture wounds
- existing infection
- animal bites

Stop use and ask a physician if

- conditions persist or worsen
- rash or other allergic reaction develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

- needed for longer than 1 week

Keep out of reach of children.

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

Directions

- shake well
- adults and children 2 years of age and older: clean affected area, spray small amount of this product on the area, not more than 1 to 3 times daily
- if bandaged, let dry first
- children under 2 years of age: consult a physician
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

SD Alcohol 40, Propylene Glycol, Disopropyl Adipate, Tocopheryl Acetate (Vitamin E Acetate)

Questions or comments?

1-888-565-BURNCARE (565-2876)
Monday through Friday, 9am-5pm

Principal Display Panel

Maximum Pain Relief

First°Degree® Burn Spray

- instant pain relief
- helps prevent infection
- cools burn on contact

Sprays at an angle!

Burns Happen. Be Prepared.™

Net Wt. 3 oz (85 g)

Drug Facts Panel



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Triclosan 0.13%.....	First aid antiseptic
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Stop use and ask a physician if ■ conditions persist or worsen ■ rash or other allergic reaction develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ needed for longer than 1 week	
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1-888-565-BURN CARE (565-2876) Monday through Friday, 9am-5pm	

Bottle Label

benzocaine, triclosan spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24330-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24330-111-85	89 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/01/2013	

Labeler - The Akshay Wellness Group, Inc. (802294863)

Revised: 7/2013

The Akshay Wellness Group, Inc.