

ANTISEPTIC- benzalkonium chloride, benzocaine spray
Afasso 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.

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.1%

Benzocaine 5.0%

Purpose

First Aid Antiseptic

Topical Pain Relief

Uses

First aid to help prevent infection and for temporary pain relief in minor cuts, scrapes and burns

Warnings

For external use only.

Flammable keep away from fire or flame.

Do not use

- near eyes or mucous membranes
- on deep or puncture wounds, animal bites, or serious burns
- over large areas of the body
- more than one week unless directed by a doctor

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask doctor if condition persists or gets worse

Directions

- clean affected area and spray 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 ask a doctor.

Inactive ingredients

isopropyl alcohol, purified water

PRINCIPAL DISPLAY PANEL - bottle label

First Aid
Antiseptic
Spray

Aids in Preventing Infections

Temporary Pain Relief
Fights Infection
Promotes Healing

#623 2 Fl. Oz. (59 mL)

Mfd. For
Afassco
MINDEN, NV 89423

<p>First Aid Antiseptic Spray</p> <p>Aids in Preventing Infections</p> <ul style="list-style-type: none"> ● Temporary Pain Relief ● Fights Infection ● Promotes Healing <p>#623 2 Fl. Oz. (59 mL) Mfd. for Afassco® MINDEN, NV 89423</p>  <p>6 70254 12623 0</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Benzalkonium Chloride 0.1%.....</td> <td>First Aid Antiseptic</td> </tr> <tr> <td>Benzocaine 5.0%.....</td> <td>Topical Pain Relief</td> </tr> </tbody> </table> <p>Uses First aid to help prevent infection and for temporary pain relief in minor cuts, scrapes and burns</p> <p>Warnings For external use only. Flammable keep away from fire or flame.</p> <p>Do not use ■ near eyes or mucous membranes ■ on deep or puncture wounds, animal bites, or serious burns ■ over large areas of the body ■ more than one week unless directed by a doctor</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Stop use and ask a doctor if condition persists or gets worse</p> <p>Directions ■ clean affected area and spray 1 to 3 times daily ■ may be covered with a sterile bandage ■ for children under 2 ask a doctor</p> <p>Inactive Ingredients isopropyl alcohol, purified water</p>	Active Ingredients	Purpose	Benzalkonium Chloride 0.1%.....	First Aid Antiseptic	Benzocaine 5.0%.....	Topical Pain Relief
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ANTISEPTIC
benzalkonium chloride, benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-5300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	1 mg in 1 mL
benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)	benzocaine	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
isopropyl alcohol (UNII: ND2M416302)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51532-5300-3	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/09/2012	

Labeler - Afasco Inc. (609982723)**Registrant** - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(51532-5300)