

# **BLISTEX FOILLE MEDICATED FIRST AID- benzocaine and chloroxylenol ointment**

**Blistex 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.*

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## **Blistex® Foille® Medicated First Aid Ointment**

### **Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Benzocaine 5.0 % (w/w)	External analgesic
Chloroxylenol 0.1 % (w/w)	Antiseptic

### **Uses**

- For the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.
- First aid to help prevent infection in minor cuts, scrapes and burns.

### **Warnings**

#### **For external use only**

#### **When using this product**

- Avoid contact with the eyes

#### **Stop use and ask a doctor if**

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.
- Do not apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

#### **Keep out of reach of children.**

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

### **Directions**

- Clean the affected area.
- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: consult a physician.

**Other information**

- **Avoid contact with clothing.** Foille may stain certain fabrics.

**Inactive ingredients**

beeswax, benzyl alcohol, calcium disodium EDTA, calcium hydroxide, ceresin, citric acid, eugenol, hydrogenated coconut oil, mono- and di-glycerides, PEG-32, purified water, sodium borate, sodium lauryl sulfate, zea mays (corn) oil

**PRINCIPAL DISPLAY PANEL - 28 g Tube Carton**

NDC 10157-9302-4

Foille®

EXTERNAL ANALGESIC / ANTISEPTIC

MEDICATED

FIRST AID OINTMENT

Fast, Soothing Relief Of Pain Due To:  
Minor Cuts, Scrapes & Burns  
Sunburn • Insect Bites

Net Wt.

1 oz. (28 g)



## BLISTEX FOILLE MEDICATED FIRST AID

benzocaine and chloroxylonol ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10157-9302
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzocaine</b> (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	5 g in 100 g
<b>Chloroxylonol</b> (UNII: 0F32U78V2Q) (Chloroxylonol - UNII:0F32U78V2Q)	Chloroxylonol	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>corn oil</b> (UNII: 8470G57WFM)	
<b>HYDROGENATED COCONUT OIL</b> (UNII: JY81OXM1OM)	

<b>yellow wax</b> (UNII: 2ZA36H0S2V)
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)
<b>water</b> (UNII: 059QF0KO0R)
<b>benzyl alcohol</b> (UNII: LKG8494WBH)
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98R082HJ)
<b>ceresin</b> (UNII: Q1LS2UJO3A)
<b>sodium borate</b> (UNII: 91MBZ8H3QO)
<b>calcium hydroxide</b> (UNII: PF5DZW74VN)
<b>edetate calcium disodium anhydrous</b> (UNII: 8U5D034955)
<b>eugenol</b> (UNII: 3T8H1794QW)
<b>sodium lauryl sulfate</b> (UNII: 368GB5141J)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9302-4	1 in 1 CARTON	03/05/2013	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10157-9302-3	1 in 1 CARTON	09/23/2016	
2		14 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/05/2013	

**Labeler** - Blistex Inc. (005126354)

### Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-9302)

Revised: 12/2021

Blistex Inc.