

## **BENZ PROTECT- benzoin resin liquid**

**Geritrex LLC**

*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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### **Benz Protect**

#### **Active Ingredient**

Benzoin Compound Tincture (Benzoin, Aloe, Storax, Tolu, Balsam, Alcohol)

#### **Intended Use**

- Forms a coating over a wound
- For protecting recurring canker sores

#### **Directions**

For adults and supervised children 2 years and older:  
Dry affected area of skin or oral mucosa. Apply with a cotton swab or gauze every 3-4 hours or as directed by your physician.

#### **Warnings**

##### **Do not**

- Use this product for more than 7 days unless directed by a dentist or doctor
- Exceed recommended dosage

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

- Sore mouth symptoms do not improve in 7 days
- Irritation, pain, or redness persists or worsens
- Swelling, rash, or fever develop

#### **Directions**

Adults and children 6 months or age and older: Dry affected area of oral mucosa. Apply the swab applicator every 3-4 hours or as directed by physician. Children under 6 months of age: Consult a dentist or Doctor

Store at 20° to 25°C (68° to 77° F) [see USP Controlled Room Temperature] in tight, light-resistant containers. Avoid exposure to direct sunlight or heat.

#### **KEEP OUT OF REACH OF CHILDREN.**

In case of accidental ingestions, seek professional assistance or contact a Poison Control Center immediately

**If pregnant or breast-feeding**, ask a health professional before use.

Drug Facts	
<b>Active Ingredient</b> Benzoin Compound Tincture (Benzoin, Aloe, Storax, Tolu Balsam, Alcohol)	<b>Purpose</b> Oral Mucosal Protectant
<b>Uses</b>	<ul style="list-style-type: none"> <li>Forms a coating over a wound</li> <li>For protecting recurring canker sores</li> </ul>
<b>Warnings</b> Do not use this product for more than 7 days unless directed by a dentist or doctor	<ul style="list-style-type: none"> <li>Do not use if you are allergic to any of the ingredients</li> <li>Do not use if you are pregnant or breastfeeding</li> <li>Do not use if you are taking any other medicine</li> <li>Do not use if you are taking any other medicine</li> <li>Do not use if you are taking any other medicine</li> </ul>
<b>Directions</b> Adults and children 6 months of age and older: Dry affected area of oral mucosa. Apply the swab applicator every 3-4 hours or as directed by physician. Children under 6 months of age: Consult a dentist or doctor.	<b>Other information</b> • Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature) in light-resistant containers. • Avoid exposure to direct sunlight and excessive heat.



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# BENZ PROTECT

benzoin resin liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54162-099
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOIN RESIN (UNII: GK21SBA74R) (BENZOIN RESIN - UNII:GK21SBA74R)	BENZOIN RESIN	100 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE (UNII: V5VD430YW9)	
LIQUIDAMBAR ORIENTALIS RESIN (UNII: 63V91G4W93)	
TOLU BALSAM (UNII: TD2LE91MBE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-099-10	3 mL in 1 POUCH; Type 0: Not a Combination Product	10/27/2017	
2	NDC:54162-099-50	150 mL in 1 BOX; Type 0: Not a Combination Product	10/27/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/31/2015	

**Labeler** - Geritrex LLC (112796248)

**Registrant** - Geritrex LLC (112796248)