

BENZOIN TINCTURE- benzoin resin liquid

Humco Holding 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.

Humco Benzoin Tincture, NF

Drug Facts

Active Ingredient

Benzoin

Purpose

Oral mucosal protectant

Use

Forms a coating over wound for protecting recurring canker sores

Warnings

For external use only. Do not swallow. Do not exceed recommended dosage.

When using this product

Children under 12 years of age should be supervised in the use of this product.

Do not use more than 7 days unless directed by a dentist or doctor.

Stop use and consult 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 develops.

Keep out of the reach of children.

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

Directions

Adult and children 6 months of age and older: Dry the affected area, with cotton swab, apply undiluted to the affected area not more than every 2 hours.

Children under 6 months of age: Consult a dentist or doctor.

Inactive Ingredients

Alcohol 77%, Aloe, Stoeax, tolu Balsam.

Questions or Comments?

1-800-662-3435

Principal Display Panel

<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredients</td> <td>Purpose</td> </tr> <tr> <td>Benzoin.....</td> <td>Oral mucosal protectant</td> </tr> <tr> <td colspan="2">Indications ■ Forms a coating over wound for protecting recurring canker sores</td> </tr> <tr> <td colspan="2">Warnings ■ Do not exceed recommended dosage</td> </tr> <tr> <td colspan="2">When using this product ■ Do not use for more than 7 days unless directed by a dentist or doctor</td> </tr> <tr> <td colspan="2">Stop use and consult a dentist or doctor promptly if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness persists or worsens ■ swelling, rash or fever develops Continued ▶</td> </tr> </table>	Active ingredients	Purpose	Benzoin.....	Oral mucosal protectant	Indications ■ Forms a coating over wound for protecting recurring canker sores		Warnings ■ Do not exceed recommended dosage		When using this product ■ Do not use for more than 7 days unless directed by a dentist or doctor		Stop use and consult a dentist or doctor promptly if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness persists or worsens ■ swelling, rash or fever develops Continued ▶		<p>BENZOIN TINCTURE ALCOHOL 79%</p> <p>HUMCOTM A trusted name in home health care</p>	<p>Safety Sealed First Aid</p> <p>USP XV</p> <p>ORAL MUCOSAL PROTECTANT</p> <p>Flammable: Keep from spark, heat or flame.</p> <p>2 FL oz (59 mL)</p>	<p>*Warning: Do not use if tamper evident seal is broken or missing. This product is sealed with either a shrink band around cap imprinted "Sealed For Your Protection" or a foil seal under cap.</p> <p>(Drug facts continued)</p> <p>Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.</p> <p>Directions ■ Adults and children 6 months of age and older: Dry the affected area. Saturate a cotton applicator with medication. Apply the undiluted medication directly to the affected area. Do not use more often than every 2 hours. ■ Children under 6 months of age: Consult a dentist or doctor</p> <p>Inactive ingredients ■ Alcohol 79%, Aloe, Storax, Tolu Balsam</p> <p>Questions or Comments? ☎1-800-662-3435</p>
Active ingredients	Purpose														
Benzoin.....	Oral mucosal protectant														
Indications ■ Forms a coating over wound for protecting recurring canker sores															
Warnings ■ Do not exceed recommended dosage															
When using this product ■ Do not use for more than 7 days unless directed by a dentist or doctor															
Stop use and consult a dentist or doctor promptly if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness persists or worsens ■ swelling, rash or fever develops Continued ▶															

REV113017

2 76272 05630 3

A34707 10 2023

BENZOIN TINCTURE				
benzoin resin liquid				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-0247	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BENZOIN RESIN (UNII: GK21SBA74R) (BENZOIN RESIN - UNII:GK21SBA74R)	BENZOIN RESIN	1000 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALCOHOL (UNII: 3K9958 V90M)			
	ALOE (UNII: V5VD430 YW9)			
	TOLU BALSAM (UNII: TD2LE9 1MBE)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-0247-92	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/01/2008	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco holding Group, inc.		825672884	manufacture(0395-0247) , analysis(0395-0247) , pack(0395-0247) , label(0395-0247)

Revised: 12/2018

Humco Holding Group, Inc.