

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.

Private Label Benzoin Tincture

Drug Facts

Active Ingredient

Benzoin

Purpose

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 for 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 reach of children.

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

Directions

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

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

Other information

Flammable: Keep away from spark, heat or flame.

Inactive Ingredients

Alcohol 77%, Aloe, Storax, Tolu Balsam

SM

sunmark™ *SAFETY SEALED
NDC 49348-139-30

benzoin tincture NFXI

Oral mucosal protectant
Alcohol 79%

Drug Facts
Active Ingredients
Benzoin.....Protectant

Purpose
Protectant

Uses: Forms a coating over a wound. For protecting recurring canker sores.

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

Stop use ask a doctor if ■ the condition persists or gets worse. ■ symptoms do not improve within 7 days. ■ pain, irritation, swelling, rash or fever develop.

When using this product ■ do not use in the eyes. ■ do not use this product for longer than 1 week unless directed by a dentist or doctor.

Keep out of the reach of children. In case of accidental ingestion seek professional or contact a Poison Control Center immediately.

Directions: ■ Adults and children 6 months of age and older: Dry the affected area. Saturate a cotton applicator with medication and apply undiluted to the affected area not more often than every 2 hours.

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

Inactive Ingredient: Aloe, Storax, Tolu Balsam, Alcohol and Purified Water.

Other Information: ■ Store at room temperature 15°-30° C (59° - 86° F) in light, light-resistant containers. ■ Avoid exposure to direct sunlight and excessive heat.

■ **FLAMMABLE: Keep away from spark, heat & flame.**

2 FL OZ (59 mL)

Distributed by McNeven
One Post Street, San Francisco, CA 94104
Money Back Guarantee

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BENZOIN TINCTURE

benzoin resin liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0395-9107 |
| 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:0395-9107-92 | 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/12/2017 | |

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(0395-9107) , analysis(0395-9107) , pack(0395-9107) , label(0395-9107) |

Revised: 6/2020

Humco Holding Group, Inc.