

BENZOIN COMPOUND TINCTURE- benzoïn 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.

Benzoïn Compound Tincture

Active Ingredient

Tincture Benzoïn compound

Intended Use

Antiseptic preparation maintains skin integrity and protects skin from adhesive and harsh body fluids. Forms a fine coating over skin, abrasions, wounds and oral lesions.

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

For external use only.
Do not apply to or near eyes. Do not swallow. In case of accidental ingestion seek professional assistance or contact poison control center immediately.

FLAMMABLE: Keep away from sparks, heat and flames.

When using this product:

Discontinue use and consult a physician if irritation persists, worsens or if swelling or rash develops. Do not use for more than 10 days unless directed by your physician.

Apply with a cotton swab or gauze every 3-4 hours

Benzoïn Resin

To be stored at room temperature 15-30°C (59-86°F). Avoid exposure to direct sunlight or heat.

KEEP OUT OF REACH OF CHILDREN.

Tincture 1oz. 1.75x3.375

54162-100-01



Benzoin Compound Tincture U.S.P.

PROTECTANT: Skin, Oral Mucosa and Minor Wounds

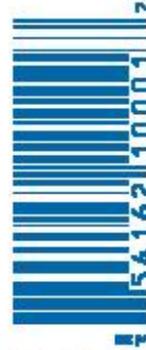
Excellent Protectant Under Adhesive Tape, Casts, Dressing and Orthotic Appliances.

Alcohol 77%
Flammable

1 FL. OZ (29 ml)

Drug Facts

Active Ingredient Tincture Benzoin compound USP 100%	Purpose Skin Protectant
Intended Use: Antiseptic preparation maintains skin integrity and protects skin from adhesive and harsh body fluids. Forms a fine coating over skin, abrasions, wounds and oral lesions.	
Warnings: For external use only. Do not apply to or near eyes. Do not swallow. In case of accidental ingestion seek professional assistance or contact poison control center immediately. FLAMMABLE: Keep away from sparks, heat and flames.	
When using this product: Discontinue use and consult a physician if irritation persists, worsens or if swelling or rash develops. Do not use for more than 10 days unless directed by your physician.	
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.	
Other Information Tincture of Benzoin Compound contains: Alcohol, Aloe, Benzoin, Storax and Tolu Balsam. To be stored at room temperature 15-30°C (59-86°F). Avoid exposure to direct sunlight or heat.	



Geritrex Corporation
144 Kingsbridge Road East
Mount Vernon, NY 10550
1-800-736-3437
www.geritrex.com

54162-100-02



Benzoin Compound Tincture U.S.P.

PROTECTANT: Skin, Oral Mucosa and Minor Wounds

Excellent Protectant Under Adhesive Tape, Casts, Dressing and Orthotic Appliances.

Alcohol 77%
Flammable

2 FL. OZ (58 ml)

Drug Facts

Active Ingredient Tincture Benzoin compound USP 100%	Purpose Skin Protectant
Intended Use: Antiseptic preparation maintains skin integrity and protects skin from adhesive and harsh body fluids. Forms a fine coating over skin, abrasions, wounds and oral lesions.	
Warnings: For external use only. Do not apply to or near eyes. Do not swallow. In case of accidental ingestion seek professional assistance or contact poison control center immediately. FLAMMABLE: Keep away from sparks, heat and flames.	
When using this product: Discontinue use and consult a physician if irritation persists, worsens or if swelling or rash develops. Do not use for more than 10 days unless directed by your physician.	
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.	
Other Information Tincture of Benzoin Compound contains: Alcohol, Aloe, Benzoin, Storax and Tolu Balsam. To be stored at room temperature 15-30°C (59-86°F). Avoid exposure to direct sunlight or heat.	



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NDC#54162-100-04 BENZOIN COMPOUND TINCTURE U.S.P.		Drug Facts	
PROTECTANT: Skin, Oral Mucosa and Minor Wounds Excellent Protectant Under Adhesive Tape, Casts, Dressing and Orthotic Appliances. Alcohol 77% Flammable 4 FL. OZ (118 ml)		Active Ingredient Tincture Benzoin compound USP 100%	
 Geritrex Corporation 144 Kingsbridge Road East Mount Vernon, New York 10550 1-800-736-3437 www.geritrex.com		Purpose Skin Protectant	
		Intended Use: Antiseptic preparation maintains skin integrity and protects skin from adhesive and harsh body fluids. Forms a fine coating over skin, abrasions, wounds and oral lesions.	
		Warnings: For external use only. Do not apply to or near eyes. Do not swallow. In case of accidental ingestion seek professional assistance or contact poison control center immediately. FLAMMABLE: Keep away from sparks, heat and flames.	
		When using this product: Discontinue use and consult a physician if irritation persists, worsens or if swelling or rash develops. Do not use for more than 10 days unless directed by your physician.	
		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.	
		Other Information Tincture of Benzoin Compound contains: Alcohol, Aloe, Benzoin, Storax and Tolu Balsam. To be stored at room temperature 15-30°C (59-86°F). Avoid exposure to direct sunlight or heat.	



BENZOIN COMPOUND TINCTURE

benzoin resin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-100
Route of Administration	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:54162-100-02	58 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-100-01	29 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	
3	NDC:54162-100-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2015	

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)**Establishment**

Name	Address	ID/FEI	Business Operations
Frutarom		237870915	manufacture(54162-100)

Revised: 1/2018

Geritrex LLC