

GALLIC ACID- gallicum acidum liquid

BioActive Nutritional

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS:

ACTIVE INGREDIENTS:

Gallicum Acidum 6X, 12X, 30X, 12C, 30C

INDICATIONS:

For temporary relief of allergic rhinitis, general fatigue, nasal congestion, joint pain, lower back pain, headaches, dyspepsia, and itching.

WARNINGS:

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

☐ **Keep out of reach of children.** ☐ In case of overdose, get medial help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

Store in a cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medial help or contact a Poison Control Center right away.

DIRECTIONS:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

BIOACTIVE NUTRITIONAL

Melbourne, FL 32935

For Nutritional Information write:

BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935

PACKAGE DISPLAY LABEL:

☐ **BioActive Homeopathic**

GALLIC ACID

1 FL OZ (30 ml)



BioActive Homeopathic

GALLIC ACID

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LOT: XXXXXXXXXX

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GALLIC ACID

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0234
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GALLIC ACID MONOHYDRATE (UNII: 48339473OT) (GALLIC ACID - UNII:632XD903SP)	GALLIC ACID MONOHYDRATE	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0234-1	30 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/23/2013	

Labeler - BioActive Nutritional (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0234) , api manufacture(43857-0234) , label(43857-0234) , pack(43857-0234)

Revised: 9/2013

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