

ALLERGEN I- potassium gluconate, glandula suprarenalis bovine, hepar bovine, arsenicum album, lycopodium clavatum, nux vomica, phosphorus, peanut, black walnut, english walnut, amygdala amara, cashew, coconut, pecan, brazil nut, tomato, solanum tuberosum, piper nigrum, eggplant (solanum melongena), rape seed oil, linum usitatissimum, sesame seed, cheese (stilton), lac vaccinum, beef, lamb, pork, chicken, egg (whole), phaseolus, allium cepa, apple, wheat, banana, strawberry, cod (gadus morhua), tuna (thunnus thynnus), 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:

Potassium Gluconate 6X, Glandula Suprarenalis Bovine 8X, Hepar Bovine 8X, Arsenicum Album 12X, Lycopodium Clavatum 12X, Nux Vomica 12X, Phosphorus 12X, Peanut 12X, 30X, Black Walnut 12X, 30X, English Walnut 12X, 30X, Amygdala Amara 12X, 30X, Cashew 12X, 30X, Coconut 12X, 30X, Pecan 12X, 30X, Brazil Nut 12X, 30X, Tomato 12X, 30X, Solanum Tuberosum 12X, 30X, Piper Nigrum 12X, 30X, Eggplant (Solanum Melongena) 12X, 30X, Rape Seed Oil 12X, 30X, Cheese (Stilton) 12X, 30X, Linum Usitatissimum 12X, 30X, Sesame Seed 12X, 30X, Lac Vaccinum 12X, 30X, Beef 12X, 30X, Lamb 12X, 30X, Pork 12X, 30X, Chicken 12X, 30X, Egg (Whole) 12X, 30X, Phaseolus 12X, 30X, Allium Cepa 12X, 30X, Apple 12X, 30X, Wheat 12X, 30X, Banana 12X, 30X, Fragaria Vesca 12X, 30X, Orange 12X, 30X, Cod (Gadus Morhua) 12X, 30X, Tuna (Thunnus Thynnus) 12X, 30X, Salmon (Salmo Salar) 12X, 30X, Crab (Cancer Pagurus) 12X, 30X, Oyster (Crassostrea Gigas) 12X, 30X, Shrimp (Crangon Crangon) 12X, 30X, Cortisone Aceticum 30X, Histaminum Hydrochloricum 30X, Hyaluronidase 30X, Interferon (Human) 30X, Serotonin (Hydrochloride) 30X.

INDICATIONS:

For temporary relief of gastrointestinal dyspepsia with flatulence and bloating, loss of weight and intolerance of certain foods.

WARNINGS:

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

Keep out of reach of children. In case of overdose, get medical 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 medical 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.

INDICATIONS:

For temporary relief of gastrointestinal dyspepsia with flatulence and bloating, loss of weight and intolerance of certain foods.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

ALLERGEN I

HOMEOPATHIC

1 FL OZ (30 ml)

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LOT:

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ALLERGEN I

HOMEOPATHIC

ACTIVE INGREDIENTS: Potassium Gluconate 6X; Glandula Suprarenalis Bovine, Hepar Bovine 8X. Arsenicum Alb, Lycopodium, Nux Vom, Phos 12X. Allium Cepa, Amygdala Amara, Apple, Banana, Beef, Black Walnut, Brazil Nut, Cashew, Cheese, Chicken, Coconut, Cod, Crab, Egg, Eggplant, English Walnut, Fragaria, Lac Vac, Lamb, Linum Usit, Orange, Oyster, Peanut, Pecan, Phaseolus, Piper Nig, Pork, Rape Seed Oil, Salmon, Sesame Seed, Shrimp, Solanum Tub, Tomato, Tuna, Wheat, 12X, 30X. Cortisone Aceticum, Histaminum Hydrochloricum, Hyaluronidase, Interferon, Serotonin 30X.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0626
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM GLUCONATE (UNII: 12H3K5QKN9) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM GLUCONATE	6 [hp_X] in 1 mL
BOS TAURUS ADRENAL GLAND (UNII: M2776SWB29) (BOS TAURUS ADRENAL GLAND - UNII:M2776SWB29)	BOS TAURUS ADRENAL GLAND	8 [hp_X] in 1 mL
HEPARIN, BOVINE (UNII: P776JQ4R2F) (HEPARIN, BOVINE - UNII:P776JQ4R2F)	HEPARIN, BOVINE	8 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	12 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
PEANUT (UNII: QE1QX6B99R) (PEANUT - UNII:QE1QX6B99R)	PEANUT	12 [hp_X] in 1 mL
BLACK WALNUT (UNII: Q2MM57BYZ1) (BLACK WALNUT - UNII:Q2MM57BYZ1)	BLACK WALNUT	12 [hp_X]

BLACK WALNUT (UNII: 02VMM57RAZJ) (BLACK WALNUT - UNII:02VMM57RAZJ)	BLACK WALNUT	in 1 mL
ENGLISH WALNUT (UNII: 1V3SHR7QB7) (ENGLISH WALNUT - UNII:1V3SHR7QB7)	ENGLISH WALNUT	12 [hp_X] in 1 mL
BITTER ALMOND (UNII: O655FW8R9A) (BITTER ALMOND - UNII:O655FW8R9A)	BITTER ALMOND	12 [hp_X] in 1 mL
CASHEW (UNII: 3H5U5CX7KO) (CASHEW - UNII:3H5U5CX7KO)	CASHEW	12 [hp_X] in 1 mL
COCONUT (UNII: 3RT3536DHY) (COCONUT - UNII:3RT3536DHY)	COCONUT	12 [hp_X] in 1 mL
PECAN (UNII: F14P91GB5F) (PECAN - UNII:F14P91GB5F)	PECAN	12 [hp_X] in 1 mL
BRAZIL NUT (UNII: XKR79OET1K) (BRAZIL NUT - UNII:XKR79OET1K)	BRAZIL NUT	12 [hp_X] in 1 mL
TOMATO (UNII: Z4KHF2C175) (TOMATO - UNII:Z4KHF2C175)	TOMATO	12 [hp_X] in 1 mL
SOLANUM TUBEROSUM WHOLE (UNII: 2A8I57T4MX) (SOLANUM TUBEROSUM WHOLE - UNII:2A8I57T4MX)	SOLANUM TUBEROSUM WHOLE	12 [hp_X] in 1 mL
GREEN PEPPERCORN (UNII: 6G53L8ESRK) (GREEN PEPPERCORN - UNII:6G53L8ESRK)	GREEN PEPPERCORN	12 [hp_X] in 1 mL
EGGPLANT (UNII: W5K7RAS4VK) (EGGPLANT - UNII:W5K7RAS4VK)	EGGPLANT	12 [hp_X] in 1 mL
CANOLA OIL (UNII: 331KBJ17RK) (CANOLA OIL - UNII:331KBJ17RK)	CANOLA OIL	12 [hp_X] in 1 mL
FLAX SEED (UNII: 4110YT348C) (FLAX SEED - UNII:4110YT348C)	FLAX SEED	12 [hp_X] in 1 mL
SESAME SEED (UNII: 7Y1255HVXR) (SESAME SEED - UNII:7Y1255HVXR)	SESAME SEED	12 [hp_X] in 1 mL
CASEIN, LACTOCOCCUS LACTIS CULTURED, PENICILLIUM ROQUEFORTI CULTURED, AGED (UNII: IYI0G2057S) (CASEIN, LACTOCOCCUS LACTIS CULTURED, PENICILLIUM ROQUEFORTI CULTURED, AGED - UNII:IYI0G2057S)	CASEIN, LACTOCOCCUS LACTIS CULTURED, PENICILLIUM ROQUEFORTI CULTURED, AGED	12 [hp_X] in 1 mL
COW MILK (UNII: 917J3173FT) (COW MILK - UNII:917J3173FT)	COW MILK	12 [hp_X] in 1 mL
BEEF (UNII: 4PIB2155QP) (BEEF - UNII:4PIB2155QP)	BEEF	12 [hp_X] in 1 mL
LAMB (UNII: FOF26T73HA) (LAMB - UNII:FOF26T73HA)	LAMB	12 [hp_X] in 1 mL
PORK (UNII: O138UB266J) (PORK - UNII:O138UB266J)	PORK	12 [hp_X] in 1 mL
CHICKEN (UNII: 0X8Q245Y7B) (CHICKEN - UNII:0X8Q245Y7B)	CHICKEN	12 [hp_X] in 1 mL
EGG (UNII: 291P45F896) (EGG - UNII:291P45F896)	EGG	12 [hp_X] in 1 mL
KIDNEY BEAN (UNII: M98C8416QO) (KIDNEY BEAN - UNII:M98C8416QO)	KIDNEY BEAN	12 [hp_X] in 1 mL
ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	12 [hp_X] in 1 mL
APPLE (UNII: B423VGH5S9) (APPLE - UNII:B423VGH5S9)	APPLE	12 [hp_X] in 1 mL
WHEAT (UNII: 4J2I0SN84Y) (WHEAT - UNII:4J2I0SN84Y)	WHEAT	12 [hp_X] in 1 mL
BANANA (UNII: 4AJZ4765R9) (BANANA - UNII:4AJZ4765R9)	BANANA	12 [hp_X] in 1 mL
FRAGARIA VESCA FRUIT (UNII: CG6IX3GCMU) (ALPINE STRAWBERRY - UNII:CG6IX3GCMU)	FRAGARIA VESCA FRUIT	12 [hp_X] in 1 mL
ORANGE (UNII: 5EVU04N5QU) (ORANGE - UNII:5EVU04N5QU)	ORANGE	12 [hp_X] in 1 mL
ATLANTIC COD (UNII: RPX7J99EXW) (ATLANTIC COD - UNII:RPX7J99EXW)	ATLANTIC COD	12 [hp_X] in 1 mL
NORTHERN BLUEFIN TUNA (UNII: 816CLQ4017) (NORTHERN BLUEFIN	NORTHERN BLUEFIN TUNA	12 [hp_X]

TUNA - UNII:816CLQ4017)	NORTHERN BLUEFIN TUNA	in 1 mL
ATLANTIC SALMON (UNII: 7062I37LB3) (ATLANTIC SALMON - UNII:7062I37LB3)	ATLANTIC SALMON	12 [hp_X] in 1 mL
EDIBLE ROCK CRAB (UNII: RLE491K17W) (EDIBLE ROCK CRAB - UNII:RLE491K17W)	EDIBLE ROCK CRAB	12 [hp_X] in 1 mL
PACIFIC OYSTER (UNII: FX2S0D3781) (PACIFIC OYSTER - UNII:FX2S0D3781)	PACIFIC OYSTER	12 [hp_X] in 1 mL
CRANGON SHRIMP (UNII: G1ZD4XB2AH) (CRANGON SHRIMP - UNII:G1ZD4XB2AH)	CRANGON SHRIMP	12 [hp_X] in 1 mL
CORTISONE ACETATE (UNII: 883WKN7W8X) (CORTISONE - UNII:V27W9254FZ)	CORTISONE ACETATE	30 [hp_X] in 1 mL
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	30 [hp_X] in 1 mL
HYALURONIDASE (BOVINE) (UNII: 8KOG53Z5EM) (HYALURONIDASE (BOVINE) - UNII:8KOG53Z5EM)	HYALURONIDASE (BOVINE)	30 [hp_X] in 1 mL
INTERLEUKIN-1 .BETA. HUMAN (UNII: X62226112J) (INTERLEUKIN-1 .BETA. HUMAN - UNII:X62226112J)	INTERLEUKIN-1 .BETA. HUMAN	30 [hp_X] in 1 mL
SEROTONIN HYDROCHLORIDE (UNII: GKN429M9VS) (SEROTONIN - UNII:333DO1RDJY)	SEROTONIN HYDROCHLORIDE	30 [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:43857-0626-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	06/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/15/2022	

Labeler - BioActive Nutritional (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0626) , api manufacture(43857-0626) , label(43857-0626) , pack(43857-0626)