

**FEMALE TONIC- condurango, humulus lupulus, agnus castus, caulophyllum thalictroides, iris versicolor, liliium tigrinum, asterias rubens, apis mellifica, calcarea fluorica, conium maculatum, ignatia amara, lac caninum, lachesis mutus, sepia cyclamen europaeum liquid
BioActive Nutritional, Inc.**

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:

Condurango 1X, Humulus Lupulus 1X, Agnus Castus 3X, Caulophyllum Thalictroides 3X, Iris Versicolor 3X, Liliium Tigrinum 3X, Asterias Rubens 6X, 12X, Apis Mellifica 12X, Calcarea Fluorica 12X, Conium Maculatum 12X, Ignatia Amara 12X, Lac Caninum 12X, Lachesis Mutus 12X, Sepia 12X, Cyclamen Europaeum 15X.

INDICATIONS:

For temporary relief of dysmenorrhea with severe ovarian pain; painful swollen breast before and during menses; menses early, profuse, black and clotted.

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 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 dysmenorrhea with severe ovarian pain; painful swollen breast before and during menses; menses early, profuse, black and clotted.

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

FEMALE TONIC

HOMEOPATHIC

2 FL OZ (60 ml)



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.

LOT:

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Melbourne, FL 32935
bioactivenutritional.com

FEMALE TONIC

HOMEOPATHIC

ACTIVE INGREDIENTS:

Condurango MT, Humulus MT, Agnus 3X, Caulophyllum 3X, Iris Vers 3X, Liliium 3X, Asterias 6X, 12X, Apis Mel 12X, Calc Fluor 12X, Conium 12X, Ignatia 12X, Lac Can 12X, Lachesis 12X, Sepia 12X, Cyclamen 15X.

INACTIVE INGREDIENTS:

Deminerlized Water,
25% Ethanol

2 FL OZ (60 ml)

INDICATIONS:

For temporary relief of dysmenorrhea with severe ovarian pain; painful swollen breast before and during menses; menses early, profuse, black and clotted.

DIRECTIONS:

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

FEMALE TONIC

condurango, humulus lupulus, agnus castus, caulophyllum thalictroides, iris versicolor, liliium tigrinum, asterias rubens, apis mellifica, calcarea fluorica, conium maculatum, ignatia amara, lac caninum, lachesis mutus, sepia cyclamen europaeum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MARSDENIA CONDURANGO BARK (UNII: R23QIR6YBA) (MARSDENIA CONDURANGO BARK - UNII:R23QIR6YBA)	MARSDENIA CONDURANGO BARK	1 [hp_X] in 1 mL
HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	1 [hp_X] in 1 mL
CHASTE TREE (UNII: 433OSF3U8A) (CHASTE TREE - UNII:433OSF3U8A)	CHASTE TREE	3 [hp_X] in 1 mL
CAULOPHYLLUM THALICTROIDES ROOT (UNII: J TJ6 HH6 YEH) (CAULOPHYLLUM	CAULOPHYLLUM	3 [hp_X]

THALICTROIDES ROOT - UNII:JTJ6HH6YEH)	THALICTROIDES ROOT	in 1 mL
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	3 [hp_X] in 1 mL
LILIUM LANCIFOLIUM WHOLE FLOWERING (UNII: X67Z2963PI) (LILIUM LANCIFOLIUM WHOLE FLOWERING - UNII:X67Z2963PI)	LILIUM LANCIFOLIUM WHOLE FLOWERING	3 [hp_X] in 1 mL
ASTERIAS RUBENS (UNII: A7FYY9Q742) (ASTERIAS RUBENS - UNII:A7FYY9Q742)	ASTERIAS RUBENS	6 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	12 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	12 [hp_X] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	12 [hp_X] in 1 mL
CANIS LUPUS FAMILIARIS MILK (UNII: G39P120JQT) (CANIS LUPUS FAMILIARIS MILK - UNII:G39P120JQT)	CANIS LUPUS FAMILIARIS MILK	12 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	12 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	12 [hp_X] in 1 mL
CYCLAMEN PURPURASCENS TUBER (UNII: G728143D8Q) (CYCLAMEN PURPURASCENS TUBER - UNII:G728143D8Q)	CYCLAMEN PURPURASCENS TUBER	15 [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:43857-0333-1	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	09/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/02/2014	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0333) , api manufacture(43857-0333) , label(43857-0333) , pack(43857-0333)

