

**HYDRATE II- coffea tosta, avena sativa, equisetum hyemale, hypericum perforatum, ginkgo biloba, germanium sesquioxide, silicea 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:

Coffea Tosta 1X, Avena Sativa 3X, Equisetum Hyemale 3X, Hypericum Perforatum 3X, Ginkgo Biloba 6X, Germanium Sesquioxide 8X, Silicea 8X.

INDICATIONS:

For temporary relief of dry mouth, dyspepsia, infrequent urination, constipation alternated with diarrhea, chronic myalgia, headaches and low back pain.

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.

DIRECTIONS:

Mix 3 parts water to one part juice, add 6 drops Hydrate II to 8 oz mixture or add 30 drops to a quart mixture. Drink 4 eight oz glasses daily in between meals. Drink Hydrate/water mixture for 6 days and then only water for one day. Repeat. After eight weeks begin drinking more pure water and less Hydrate/water mixture. Consult a physician for use in children under 12 years of age.

INACTIVE INGREDIENTS:

Celandine (Leaf, Stem, Flower) Chelidonium Majus, Beet (Root) Beta Vulgaris, Blessed Thistle (Leaf, Stem, Flower) Cnicus Benedictus, Boldo (Leaf) Peumus Boldus, Dandelion (Root) Taraxacum Officinale, Parsley (Leaf) Petroselinum Crispum, Demineralized Water, 25% Ethanol.

KEEP OUT OF REACH OF CHILDREN:

In case of overdose, get medical help or contact a Poison Control Center right away.

INDICATIONS:

For temporary relief of dry mouth, dyspepsia, infrequent urination, constipation alternated with diarrhea, chronic myalgia, headaches and low back pain.

QUESTIONS:

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

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

HYDRATE II

HOMEOPATHIC

2 FL OZ (60 ml)



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LOT:

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HYDRATE II HOMEOPATHIC

ACTIVE INGREDIENTS:

Coffea Tosta MT, Avena Sativa 3X, Equisetum Hyemale 3X, Hypericum Perforatum 3X, Ginkgo Biloba 6X, Germanium Sesquioxide 8X, Silicea 8X.

INACTIVE INGREDIENTS:

Beet (Root) Extract, Blessed Thistle (Leaf, Stem, Flower) Extract, Boldo (Leaf) Extract, Celandine (Leaf, Stem, Flower) Extract, Dandelion (Root) Extract, Demineralized Water, 25% Ethanol, Parsley (Leaf) Extract.

2 FL OZ (60 ml)

INDICATIONS:

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HYDRATE II

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:43857-0080

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COFFEA ARABICA SEED, ROASTED (UNII: 9H58JRT35E) (COFFEA ARABICA SEED, ROASTED - UNII:9H58JRT35E)	COFFEA ARABICA SEED, ROASTED	1 [hp_X] in 1 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	3 [hp_X] in 1 mL
EQUISETUM HYEMALE WHOLE (UNII: 59677RXH25) (EQUISETUM HYEMALE WHOLE - UNII:59677RXH25)	EQUISETUM HYEMALE WHOLE	3 [hp_X] in 1 mL
HYPERICUM PERFORATUM WHOLE (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM WHOLE - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM WHOLE	3 [hp_X] in 1 mL
GINKGO (UNII: 19FUJ2C58T) (GINKGO - UNII:19FUJ2C58T)	GINKGO	6 [hp_X] in 1 mL
GERMANIUM SESQUIOXIDE (UNII: 96WE91N25T) (GERMANIUM SESQUIOXIDE - UNII:96WE91N25T)	GERMANIUM SESQUIOXIDE	8 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	8 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHELIDONIUM MAJUS WHOLE (UNII: 7E889U5RNN)	
BEET (UNII: N487KM8COK)	
CENTAUREA BENEDICTA (UNII: 6L5ZL09795)	
PEUMUS BOLDUS LEAF (UNII: Q4EVM09M3O)	
TARAXACUM OFFICINALE ROOT (UNII: 9DE5YCO0RU)	
PARSLEY (UNII: 58FMD0Q0EV)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0080-1	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/18/2013	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0080) , api manufacture(43857-0080) , label(43857-0080) , pack(43857-0080)

Revised: 9/2023

BioActive Nutritional, Inc.