

GYNOBALANCE- dehydroepiandrosterone, estradiol, pregnenolone, progesterone, testosterone 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:

DHEA (Dehydroepiandrosterone) 6X, Estradiol 8X, Pregnenolone 8X, Progesterone 8X, Testosterone 8X.

INDICATIONS:

For temporary relief of symptoms due to menopausal hot flashes, loss of libido; may enhance calcium metabolism, feelings of well-being and mental clarity.

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:

Three sprays per day. Hold in mouth for two minutes.

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INACTIVE INGREDIENTS:

Citric Acid, Demineralized Water, Ethanol 0.07%, Glycerin, Sodium Benzoate.

QUESTIONS:

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

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

GYNOBALANCE

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0033
Route of Administration	ORAL	DEA Schedule	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRASTERONE (UNII: 459AG36T1B) (PRASTERONE - UNII:459AG36T1B)	PRASTERONE	6 [hp_X] in 1 mL

ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	8 [hp_X] in 1 mL
PREGNENOLONE (UNII: 73R90F7MQ8) (PREGNENOLONE - UNII:73R90F7MQ8)	PREGNENOLONE	8 [hp_X] in 1 mL
PROGESTERONE (UNII: 4G7DS2Q64Y) (PROGESTERONE - UNII:4G7DS2Q64Y)	PROGESTERONE	8 [hp_X] in 1 mL
TESTOSTERONE (UNII: 3XMK78S47O) (TESTOSTERONE - UNII:3XMK78S47O)	TESTOSTERONE	8 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0033-1	30 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		01/18/2013	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0033) , api manufacture(43857-0033) , label(43857-0033) , pack(43857-0033)

Revised: 8/2023

BioActive Nutritional, Inc.