

MELATONIN- melatonin 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 INGREDIENT:

Melatonin 6X.

INDICATIONS:

For temporary relief of fatigue, irritability, insomnia, and exhaustion.

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.

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For temporary relief of fatigue, irritability, insomnia, and exhaustion.

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

MELATONIN 6X

HOMEOPATHIC

1 FL OZ (30 ml)



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MELATONIN

melatonin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0511
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MELATONIN (UNII: JL5DK93RCL) (MELATONIN - UNII:JL5DK93RCL)	MELATONIN	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:43857-0511-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/22/2019	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0511) , api manufacture(43857-0511) , label(43857-0511) , pack(43857-0511)

Revised: 3/2019

BioActive Nutritional, Inc.