ANDROBALANCE- dhea (dehydroepiandrosterone) pregnenolone, progesterone, testosterone spray 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, Pregnenolone 8X, Progesterone 8X, Testosterone 8X.

INDICATIONS:

For temporary relief of symptoms due to male andropause such as: lethargy, muscle weakness & aches, and decrease in libido.

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:

One spray three times 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

ANDROBALANCE

HOMEOPATHIC

1 FL OZ (30 ml)

BIOActiveNutritional

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LOT:

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Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0284		
Route of Administration	ORAL	DEA Schedule	CIII		
Active Ingredient/Active Moiety					

			Chara an a bh
	Ingredient Name	Basis of Strengt	-
	III: 459AG36T1B) (PRASTERONE - UNII:459AG36T1B)	PRASTERONE	6 [hp_X] in 1 mL
PREGNENOLONE	MQ8) PREGNENOLONE	8 [hp_X] in 1 mL	
PROGESTERONE	Q64Y) PROGESTERONE	8 [hp_X] in 1 mL	
TESTOSTERONE	5470) TESTOSTERONE	8 [hp_X] in 1 mL	
Inactive Ingr	edients		
		Strength	
GLYCERIN (UNII: P			
SODIUM BENZOA			
CITRIC ACID MON			
WATER (UNII: 059			
ALCOHOL (UNII: 3			
Packaging			
# Item Code	Package Description	Marketing Start M Date	larketing End Date
1 NDC:43857- 0284-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/13/2017	
Marketing	Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start M Date	larketing End Date
unapproved homeopathic		02/24/2014	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment					
Name	Address	ID/FEI	Business Operations		
Apotheca Company		844330915	manufacture(43857-0284) , api manufacture(43857-0284) , label(43857-0284) , pack(43857-0284)		

Revised: 6/2023

BioActive Nutritional, Inc.