

RELAXOFORCE- humulus lupulus, passiflora incarnata, valeriana officinalis, calcarea carbonica, coffea tosta, ignatia amara, kali phosphoricum, moschus, nux vomica, phosphorus, pulsatilla (pratensis) 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:

Humulus Lupulus 3X, Passiflora Incarnata 3X, Valeriana Officinalis 3X, Calcarea Carbonica 12X, Coffea Tosta 12X, Ignatia Amara 12X, Kali Phosphoricum 12X, Moschus 12X, Nux Vomica 12X, Phosphorus 12X, Pulsatilla (Pratensis) 12X.

INDICATIONS:

For temporary relief of anxiety and stress.

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:

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 anxiety and stress.

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

RELAXOFORCE

HOMEOPATHIC

1 FL OZ (30 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:

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

RELAXOFORCE

HOMEOPATHIC

ACTIVE INGREDIENTS:
Humulus Lupulus 3X, Passiflora Incarnata 3X, Valeriana Officinalis 3X, Calcarea Carbonica 12X, Coffea Tosta 12X, Ignatia Amara 12X, Kali Phosphoricum 12X, Moschus 12X, Nux Vomica 12X, Phosphorus 12X, Pulsatilla 12X.

INACTIVE INGREDIENTS:
Demineralized Water,
25% Ethanol

1 FL OZ (30 ml)

INDICATIONS:
For temporary relief of anxiety and stress.

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

RELAXOFORCE

humulus lupulus, passiflora incarnata, valeriana officinalis, calcarea carbonica, coffea tosta, ignatia amara, kali phosphoricum, moschus, nux vomica, phosphorus, pulsatilla (pratensis) liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0545
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HORS (UNII: 01G73H6UH3) (HORS - UNII:01G73H6UH3)		HORS	3 [hp X]

ROPS (UNII: 01G73H6H63) (ROPS - UNII:01G73H6H63)	ROPS	in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	3 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 mL
COFFEA ARABICA SEED, ROASTED (UNII: 9H58JRT35E) (COFFEA ARABICA SEED, ROASTED - UNII:9H58JRT35E)	COFFEA ARABICA SEED, ROASTED	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
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	DIBASIC POTASSIUM PHOSPHATE	12 [hp_X] in 1 mL
MOSCHUS MOSCHIFERUS MUSK SAC RESIN (UNII: 8KFK4W7KP7) (MOSCHUS MOSCHIFERUS MUSK SAC RESIN - UNII:8KFK4W7KP7)	MOSCHUS MOSCHIFERUS MUSK SAC RESIN	12 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	12 [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:43857-0545-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/19/2020	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0545) , api manufacture(43857-0545) , label(43857-0545) , pack(43857-0545)

