

FIBROCANE CALM- aconitum napellus, aesculus hippocastanum, flos, arsenicum album, avena sativa, belladonna, camphora, cinchona officinalis, coffea cruda, cypridium pubescens, hyoscyamus niger, ignatia amara, passiflora incarnata, pulsatilla, valeriana officinalis liquid Premier Bioceuticals LLC.

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.

FibroCane CALM

Indications: FibroCane Calm temporarily relieves symptoms due to occasional sleeplessness: restlessness, nervousness, exhaustion, excitability, worry or inability to fall or stay asleep.

Active Ingredients: Aconitum napellus, Aesculus hippocastanum, flos, Arsenicum album, Avena sativa, Belladonna, Camphora, Cinchona officinalis, Coffea cruda, Cypridium pubescens, Hyoscyamus niger, Ignatia amara, Passiflora incarnata, Pulsatilla, Valeriana officinalis. Equal volumes of each ingredient at 10X, 30X, LM1 potencies.

Inactive Ingredients:

Citric acid, potassium sorbate, purified water.

Directions: Initially, depress pump until primed. Hold close and spray directly into your mouth. Take 2 pump sprays twice daily, morning and evening. Additional sprays may be taken during the night as needed. For ages 12 and above.

Warnings

- **Stop use and call a doctor** if symptoms persist or worsen.
- **If pregnant or breast-feeding**, consult a healthcare professional before use.
- **Keep out of reach of children.**

Other Information:

Tamper resistant for your protection. Use only if safety seal is intact.

FibroCane Calm temporarily relieves symptoms due to occasional sleeplessness:

- restlessness
- nervousness
- exhaustion
- excitability
- worry or inability to fall or stay asleep

DIRECTIONS: Initially, depress pump until primed. Hold close and spray directly into your mouth. Take 2 pump sprays twice daily, morning and evening. Additional sprays may be taken during the night as needed. For ages 12 and above.

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To reorder call (888) 887-9778 or visit www.fibrocanecalm.com



NDC 57850-0001-1



A remedy that naturally helps your body rest, restore & rejuvenate.

Homeopathic Medicine
1 fluid ounce

INDICATIONS: FibroCane Calm temporarily relieves symptoms due to occasional sleeplessness: restlessness, nervousness, exhaustion, excitability, worry, or inability to fall or stay asleep.

ACTIVE INGREDIENTS: Aconitum napellus, Aesculus hippocastanum, flos, Arsenicum album, Avena sativa, Belladonna, Camphora, Cinchona officinalis, Coffea cruda, Cypripedium pubescens, Hyoscyamus niger, Ignatia amara, Passiflora incarnata, Pulsatilla, Valeriana officinalis. Equal volumes of each ingredient at 10X, 30X, LM1 potencies.

INACTIVE INGREDIENTS: Citric acid, potassium sorbate, purified water.

Premier Bioceuticals, PO Box 78391, Indianapolis, IN 46278

FIBROCANE CALM

aconitum napellus, aesculus hippocastanum, flos, arsenicum album, avena sativa, belladonna, camphora, cinchona officinalis, coffea cruda, cypripedium pubescens, hyoscyamus niger, ignatia amara, passiflora incarnata, pulsatilla, valeriana officinalis liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57850-0001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	10 [hp_X] in 29.6 mL
AESCULUS HIPPOCASTANUM FLOWER (UNII: KK0Z92II8M) (AESCULUS HIPPOCASTANUM FLOWER - UNII:KK0Z92II8M)	AESCULUS HIPPOCASTANUM FLOWER	10 [hp_X] in 29.6 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	10 [hp_X] in 29.6 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	10 [hp_X] in 29.6 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	10 [hp_X] in 29.6 mL
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	10 [hp_X] in 29.6 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	10 [hp_X] in 29.6 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	10 [hp_X] in 29.6 mL
CYPRIPEDIUM PARVIFOLUM ROOT (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFOLUM ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFOLUM ROOT	10 [hp_X] in 29.6 mL
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	10 [hp_X] in 29.6 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	10 [hp_X] in 29.6 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA	PASSIFLORA INCARNATA	10 [hp_X]

INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	FLOWERING TOP	in 29.6 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	10 [hp_X] in 29.6 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	10 [hp_X] in 29.6 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57850-0001-1	29.6 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/31/2013	

Labeler - Premier Bioceticals LLC. (027714978)

Registrant - Premier Bioceticals LLC. (027714978)

Revised: 6/2014

Premier Bioceticals LLC.