

PROSTATONE- echinacea (angustifolia), sabal serrulata, sarsaparilla (smilax regelii), solidago virgaurea, zincum sulphuricum, phytolacca decandra, hydrastis canadensis, orchitinum (suis), prostate (suis), clematis erecta, phosphoricum acidum, pulsatilla (vulgaris) 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:

Echinacea (Angustifolia) 3X, Sabal Serrulata 3X, Sarsaparilla (Smilax Regelii) 3X, Solidago Virgaurea 3X, Zincum Sulphuricum 3X, Phytolacca Decandra 4X, Hydrastis Canadensis 5X, Orchitinum (Suis) 8X, Prostate (Suis) 8X, Clematis Erecta 12X, Phosphoricum Acidum 12X, Pulsatilla (Vulgaris) 12X.

INDICATIONS:

For temporary relief of pain in the scrotum, testicles tender & swollen.

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.

INDICATIONS:

For temporary relief of pain in the scrotum, testicles tender & swollen.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

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

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

PROSTATONE

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

PROSTATONE
HOMEOPATHIC

ACTIVE INGREDIENTS:
Echinacea 3X, Sabal Serrulata 3X, Sarsaparilla 3X, Solidago Virgaurea 3X, Zincum Sulphuricum 3X, Phytolacca Decandra 4X, Hydrastis Canadensis 5X, Orchitinum 8X, Prostate 8X, Clematis Erecta 12X, Phosphoricum Acidum 12X, Pulsatilla 12X.

INACTIVE INGREDIENTS:
Demineralized Water,
25% Ethanol

1 FL OZ (30 ml)

INDICATIONS:
For temporary relief of pain in the scrotum, testicles tender & swollen.

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

PROSTATONE

echinacea (angustifolia), sabal serrulata, sarsaparilla (smilax regelii), solidago virgaurea, zincum sulphuricum, phytolacca decandra, hydrastis canadensis, orchitinum (suis), prostate (suis), clematis erecta, phosphoricum acidum, pulsatilla (vulgaris) liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0492
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)		ECHINACEA ANGUSTIFOLIA	3 [hp_X] in 1 mL
SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)		SAW PALMETTO	3 [hp_X] in 1 mL
SARSAPARILLA (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)		SARSAPARILLA	3 [hp_X] in 1 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)		SOLIDAGO VIRGAUREA FLOWERING TOP	3 [hp_X] in 1 mL
ZINC SULFATE HEPTAHYDRATE (UNII: N57J12K7WP) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	3 [hp_X] in 1 mL

PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8 VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8 VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	5 [hp_X] in 1 mL
SUS SCROFA TESTICLE (UNII: KM02613O28) (SUS SCROFA TESTICLE - UNII:KM02613O28)	SUS SCROFA TESTICLE	8 [hp_X] in 1 mL
SUS SCROFA PROSTATE (UNII: O6UD3347K2) (SUS SCROFA PROSTATE - UNII:O6UD3347K2)	SUS SCROFA PROSTATE	8 [hp_X] in 1 mL
CLEMATIS RECTA FLOWERING TOP (UNII: 396421SP9F) (CLEMATIS RECTA FLOWERING TOP - UNII:396421SP9F)	CLEMATIS RECTA FLOWERING TOP	12 [hp_X] in 1 mL
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	12 [hp_X] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	PULSATILLA VULGARIS	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:43857-0492-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/29/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/29/2018	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0492) , api manufacture(43857-0492) , label(43857-0492) , pack(43857-0492)

Revised: 8/2018

BioActive Nutritional, Inc.