PROSTATONE- hydrangea arborescens, sabal serrulata, chimaphila umbellata, clematis erecta, conium maculatum, pareira brava, pulsatilla (pratensis), thuja occidentalis, triticum occidentalis, triticum repens, staphysagria, zincum metallicum liquid Energique, 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:

(in each drop): 12.46% of Clematis Erecta 12X, Conium Maculatum 12X, Pareira Brava 12X, Pulsatilla (Pratensis) 12X, Staphysagria 12X, Thuja Occidentalis 12X, Triticum Repens 12X, Zincum Metallicum 12X; 0.10% of Chimaphila Umbellata 4X, Hydrangea Arborescens 3X, Sabal Serrulata 3X.

INDICATIONS:

May temporarily relieve pain down thighs during efforts to urinate, great straining and constant urging when urinating.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

WARNINGS:

If pregnant or breastfeeding, ask a health 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.

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:

Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

May temporarily relieve pain down thighs during efforts to urinate, great straining and constant urging when urinating.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

INACTIVE INGREDIENTS:

Demineralized water, 20% Ethanol.

QUESTIONS:

Dist. by Energique, Inc. 201 Apple Blvd. Woodbine, IA 51579 **800.868.8078**

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

PROSTATONE

1 fl. oz. (30 ml)

WARNINGS: If pregnant or breastfeeding, ask a health 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.

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LOT: XXXXXXX

PROSTATONE

hydrangea arborescens, sabal serrulata, chimaphila umbellata, clematis erecta, conium maculatum, pareira brava, pulsatilla (pratensis), thuja occidentalis, triticum occidentalis, triticum repens, staphysagria, zincum metallicum liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:449 11-0 494 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDRANGEA ARBORESCENS ROOT (UNII: SFK828Q2DE) (HYDRANGEA ARBORESCENS ROOT - UNII:SFK828Q2DE)	HYDRANGEA ARBORESCENS ROOT	3 [hp_X] in 1 mL	
CAMADAI METTO (HAHI, 17555, IIOMOOC) (CAMADAI METTO HAHILIZATATIOMOOC)	CAMDALMETTO	3 [hp_X]	

SAW FALIMETTO (OME 1/ MANTEMONS) (SWA LYPETTO - OMET') MANTEMONS)	SAW FALMETIO	in 1 mL
CHIMAPHILA UMBELLATA (UNII: WCK21A9W9J) (CHIMAPHILA UMBELLATA - UNII:WCK21A9W9J)	CHIMAPHILA UMBELLATA	4 [hp_X] in 1 mL
CLEMATIS RECTA FLO WERING TOP (UNII: 396421SP9F) (CLEMATIS RECTA FLOWERING TOP - UNII:396421SP9F)	CLEMATIS RECTA FLOWERING TOP	12 [hp_X] in 1 mL
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	12 [hp_X] in 1 mL
CHONDRODENDRON TO MENTO SUM ROOT (UNII: 395A3P448Z) (CHONDRODENDRON TOMENTO SUM ROOT - UNII:395A3P448Z)	CHONDRODENDRON TOMENTOSUM ROOT	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS (UNII: 8E272251DI) (ANEMONE PRATENSIS - UNII:8E272251DI)	PULSATILLA PRATENSIS	12 [hp_X] in 1 mL
THUJA O CCIDENTALIS LEAFY TWIG (UNII: 1NT28 V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28 V9397)	THUJA OCCIDENTALIS LEAFY TWIG	12 [hp_X] in 1 mL
ELYMUS REPENS ROOT (UNII: 3IXW0F6P8W) (ELYMUS REPENS ROOT - UNII:3IXW0F6P8W)	ELYMUS REPENS ROOT	12 [hp_X] in 1 mL
DELPHINIUM STAPHIS AGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHIS AGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHIS AGRIA SEED	12 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	12 [hp_X] in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		

Packaging					
	# Ite	m Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:4		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	0 4/11/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/11/2019	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0494), api manufacture(44911-0494), label(44911-0494), pack(44911-0494)

Revised: 4/2019 Energique, Inc.