

PROSTATONE- chimaphila umbellata, hydrangea arborescens, sabal serrulata, clematis erecta, conium maculatum, pareira brava, pulsatilla (pratensis), thuja occidentalis, triticum occidentale, 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:

Chimaphila Umbellata 3X, Hydrangea Arborescens 3X, Sabal Serrulata 3X, Clematis Erecta 12X, Conium Maculatum 12X, Pareira Brava 12X, Pulsatilla (Pratensis) 12X, Thuja Occidentalis 12X, Triticum Occidentalis 12X, Triticum Repens 12X, Staphysagria 12X, Zincum Metallicum 12X.

INDICATIONS:

For temporary relief of pain down thighs during efforts to urinate, great straining and constant urging when urinating.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

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, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For temporary relief of pain down thighs during efforts to urinate, great straining and constant urging when urinating.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

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 breast-feeding, 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.

INDICATIONS: For temporary relief of pain down thighs during efforts to urinate, great straining and constant urging when urinating.**

**These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

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

800.869.8078

LOT: XXXXXX



HOMEOPATHIC REMEDY

PROSTATONE™

1 fl. oz. (30 ml) 20% Ethanol

Active Ingredients: Chimaphila Umbellata 3X, Hydrangea Arborescens 3X, Sabal Serrulata 3X, Clematis Erecta 12X, Conium Maculatum 12X, Pareira Brava 12X, Pulsatilla 12X, Thuja Occidentalis 12X, Triticum Repens 12X, Staphysagria 12X, Zincum Metallicum 12X.

Inactive Ingredients:
Demineralized water, 20% Ethanol.

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

PROSTATONE

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:449 11-0311
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHIMAPHILA UMBELLATA (UNII: WCK21A9W9J) (CHIMAPHILA UMBELLATA - UNII:WCK21A9W9J)	CHIMAPHILA UMBELLATA	3 [hp_X] in 1 mL
HYDRANGAEA ARBORESCENS ROOT (UNII: SFK828Q2DE) (HYDRANGAEA	HYDRANGAEA	3 [hp_X]

ARBORESCENS ROOT - UNII:SFK828Q2DE)	ARBORESCENS ROOT	in 1 mL
SAW PALMETTO (UNII: J7WWH9M8QS) (SAW PALMETTO - UNII:J7WWH9M8QS)	SAW PALMETTO	3 [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
CONIUM MACULATUM FLOWERING TOP (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	12 [hp_X] in 1 mL
CHONDRODENDRON TOMENTOSUM ROOT (UNII: 395A3P448Z) (CHONDRODENDRON TOMENTOSUM ROOT - UNII:395A3P448Z)	CHONDRODENDRON TOMENTOSUM ROOT	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS (UNII: 8E272251DI) (PULSATILLA PRATENSIS - UNII:8E272251DI)	PULSATILLA PRATENSIS	12 [hp_X] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	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 STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA 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: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:449 11-0311-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	12/11/2015	08/14/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/11/2015	08/14/2022

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0311) , api manufacture(449 11-0311) , label(449 11-0311) , pack(449 11-0311)