

**COLOSTAT- rhamnus purshiana, spigelia anthelmia, taraxacum officinale, cajuputum, hydrastis canadensis, alumina, cina, cinchona officinalis, lycopodium clavatum, magnesia phosphorica, mandragora officinarum, nux vomica 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): 14.21% of Alumina 12X, Cina 12X, Cinchona Officinalis 12X, Hydrastis Canadensis 6X, Lycopodium Clavatum 12X, Magnesia Phosphorica 12X, Nux Vomica 12X; 0.10% of Cajuputum 6X, Mandragora Officinarum 12X, Rhamnus Purshiana 3X, Spigelia Anthelmia 3X, Taraxacum Officinale 3X.

INDICATIONS:

May temporarily relieve flatulence associated with constipation.**

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

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.

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.

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INACTIVE INGREDIENTS:

Demineralized water, 20% Ethanol

QUESTIONS:

Dist. by Energique, Inc.
201 Apple Blvd
Woodbine, IA 51579 800.869.8078

PACKAGE LABEL DISPLAY:

ENERGIQUE
SINCE 1987
HOMEOPATHIC REMEDY
COLOSTAT
1 fl. oz. (30 ml)

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HOMEOPATHIC REMEDY

COLOSTAT™

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

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LOT: XXXXXX
MFD: MM/YY



COLOSTAT

rhamnus purshiana, spigelia anthelmia, taraxacum officinale, cajuputum, hydrastis canadensis, alumina, cina, cinchona officinalis, lycopodium clavatum, magnesia phosphorica, mandragora officinarum, nux vomica liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:449 11-0411
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FRANGULA PURSHIANA BARK (UNII: 4VBP01X99F) (FRANGULA PURSHIANA BARK - UNII:4VBP01X99F)	FRANGULA PURSHIANA BARK	3 [hp_X] in 1 mL
SPIGELIA ANTHELMIA (UNII: WYT05213GE) (SPIGELIA ANTHELMIA - UNII:WYT05213GE)	SPIGELIA ANTHELMIA	3 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	3 [hp_X] in 1 mL
CAJUPUT OIL (UNII: J3TO6BUQ37) (CAJUPUT OIL - UNII:J3TO6BUQ37)	CAJUPUT OIL	6 [hp_X] in 1 mL

GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	12 [hp_X] in 1 mL
ALUMINUM OXIDE (UNII: LM26O6933) (ALUMINUM OXIDE - UNII:LM26O6933)	ALUMINUM OXIDE	12 [hp_X] in 1 mL
ARTEMISIA CINA PRE-FLOWERING TOP (UNII: 28M1820ACT) (ARTEMISIA CINA FLOWER - UNII:28M1820ACT)	ARTEMISIA CINA PRE-FLOWERING TOP	12 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	12 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	12 [hp_X] in 1 mL
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	12 [hp_X] in 1 mL
MANDRAGORA OFFICINARUM ROOT (UNII: I2XCB174VB) (MANDRAGORA OFFICINARUM ROOT - UNII:I2XCB174VB)	MANDRAGORA OFFICINARUM ROOT	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

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 11-0411-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	12/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/30/2016	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0411) , api manufacture(449 11-0411) , label(449 11-0411) , pack(449 11-0411)