

**TOBACCOSTAT- avena sativa, valeriana officinalis, capsicum annuum, paullinia sorbilis, lobelia inflata, tabacum, cadmium sulphuratum, caladium seguinum, daphne indica, nux vomica, phosphoricum acidum, spigelia anthelmia, staphysagria 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): 12.43% of Cadmium Sulphuratum 12X, Caladium Seguinum 12X, Daphne Indica 12X, Lobelia Inflata 12X, Nux Vomica 12X, Phosphoricum Acidum 12X, Spigelia Anthelmia 12X, Staphysagria 12X; 0.10% of Avena Sativa 1X, Capsicum Annuum 3X, Lobelia Inflata 3X, Paullinia Sorbilis 3X, Tabacum 4X, Valeriana Officinalis 1X.

INDICATIONS:

May temporarily relieve symptoms caused by tobacco intoxication, such as headache and dizziness.**

**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 symptoms caused by tobacco intoxication, such as headache and dizziness.**

**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 **800.869.8078**

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

TOBACCOSTAT

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.

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LOT: XXXXXX MFD: MM/YY

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HOMEOPATHIC REMEDY

TOBACCOSTAT™

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

Active Ingredients (in each drop):

12.43% of Cadmium Sulphuratum 12X, Caladium Seguinum 12X, Daphne 12X, Lobelia Inf 12X, Nux Vom 12X, Phosphoricum Ac 12X, Spigelia Anth 12X, Staphysag 12X; 0.10% of Avena 1X, Capsicum 3X, Lobelia Inf 3X, Paullinia Sorb 3X, Tabacum 4X, Valeriana 1X.

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 for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.



TOBACCOSTAT

avena sativa, valeriana officinalis, capsicum annuum, paullinia sorbilis, lobelia inflata, tabacum, cadmium sulphuratum, caladium seguinum, daphne indica, nux vomica, phosphoricum acidum,

spigelia anthelmia, staphysagria liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0458
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	1 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	3 [hp_X] in 1 mL
PAULLINIA CUPANA SEED (UNII: C21GE7524R) (PAULLINIA CUPANA SEED - UNII:C21GE7524R)	PAULLINIA CUPANA SEED	3 [hp_X] in 1 mL
LOBELIA INFLATA WHOLE (UNII: 9PP1T3TC5U) (LOBELIA INFLATA - UNII:9PP1T3TC5U)	LOBELIA INFLATA WHOLE	3 [hp_X] in 1 mL
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	4 [hp_X] in 1 mL
CADMIUM SULFIDE (UNII: 057EZR4Z7Q) (CADMIUM CATION - UNII:T494FZ4G8G)	CADMIUM SULFIDE	12 [hp_X] in 1 mL
DIEFFENBACHIA SEGUINE (UNII: 01800C6E6B) (DIEFFENBACHIA SEGUINE - UNII:01800C6E6B)	DIEFFENBACHIA SEGUINE	12 [hp_X] in 1 mL
DAPHNE ODORA BARK (UNII: JSJ34YQJ5D) (DAPHNE ODORA BARK - UNII:JSJ34YQJ5D)	DAPHNE ODORA BARK	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
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	12 [hp_X] in 1 mL
SPIGELIA ANTHELMIA WHOLE (UNII: WYT05213GE) (SPIGELIA ANTHELMIA WHOLE - UNII:WYT05213GE)	SPIGELIA ANTHELMIA WHOLE	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:44911-0458-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	06/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved homeopathic		06/15/2018	
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Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0458) , api manufacture(44911-0458) , label(44911-0458) , pack(44911-0458)

Revised: 8/2023

Energique, Inc.