

SMOGSTAT- echinacea (angustifolia), hypericum perforatum, hydrastis canadensis, symphytum officinale, arsenicum album, carbo vegetabilis, causticum, kali carbonicum, natrum sulphuricum, phosphorus, puls atilla (pratensis), silicea 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): 9.98% of Arsenicum Album 12X, Carbo Vegetabilis 12X, Causticum 12X, Hydrastis Canadensis 6X, Kali Carbonicum 12X, Natrum Sulphuricum 12X, Phosphorus 12X, Pulsatilla (Pratensis) 12X, Silicea 12X, Symphytum Officinale 6X; 0.10% of Echinacea (Angustifolia) 3X, Hypericum Perforatum 3X.

INDICATIONS:

May temporarily relieve symptoms associated with exposure to pollutants, such as cough with expectorations.**

**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.

INDICATIONS:

May temporarily relieve symptoms associated with exposure to pollutants, such as cough with expectorations.**

**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

Smogstat

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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HOMEOPATHIC REMEDY

SMOGSTAT™

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

Active Ingredients (in each drop):
9.98% of Arsenicum Album 12X,
Carbo Vegetabilis 12X, Causticum
12X, Hydrastis Canadensis 6X, Kali
Carbonicum 12X, Natrum Sulphuricum
12X, Phosphorus 12X, Pulsatilla 12X,
Silicea 12X, Symphytum Officinale 6X;
0.10% of Echinacea 3X, Hypericum
Perforatum 3X.

Inactive Ingredients:
Demineralized water, 20% Ethanol.

DIRECTIONS: Adults and children 6
to 18 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.

LOT: XXXXXX

SMOGSTAT

echinacea (angustifolia), hypericum perforatum, hydrastis canadensis, symphytum officinale, arsenicum album, carbo vegetabilis, causticum, kali carbonicum, natrum sulphuricum, phosphorus, pulsatilla (pratensis), silicea liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0561
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5U8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5U8)	ECHINACEA ANGUSTIFOLIA WHOLE	3 [hp_X] in 1 mL
HYPERICUM PERFORATUM WHOLE (UNII: XK4IUX8MNB) (HYPERICUM	HYPERICUM PERFORATUM	3 [hp_X]

PERFORATUM - UNII:XK4IUX8MNB)	WHOLE	in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10)	ACTIVATED CHARCOAL	12 [hp_X] in 1 mL
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)	CAUSTICUM	12 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	12 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DJ) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DJ)	PULSATILLA PRATENSIS WHOLE	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	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:449 11-0561-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	12/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/07/2020	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-056 1) , api manufacture(449 11-056 1) , label(449 11-056 1) , pack(449 11-056 1)