

SPLEENEX V- aralia quinquefolia, potassium gluconate, ginkgo biloba, magnesium gluconicum dihydricum, pancreas suis, spleen (suis), stomach (suis), germanium sesquioxide, cuprum metallicum, zincum metallicum, alpha-ketoglutaricum acidum, citricum acidum, fumaricum acidum, magnesia phosphorica, malicum acidum, pyruvic acid, succinicum acidum, naphthochinonum, aconiticum acidum, cis-, natrum oxalaceticum 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): 2.47% of Ginkgo Biloba 6X; Aralia Quinquefolia 6X, 12X, 30X; Alpha-Ketoglutaricum Acidum 8X, 12X, 30X, Citricum Acidum 8X, 12X, 30X, Fumaricum Acidum 8X, 12X, 30X, Pyruvic Acid 8X, 12X, 30X, Succinicum Acidum 8X, 12X, 30X; Cuprum Metallicum 12X, Zincum Metallicum 12X; Magnesia Phosphorica 12X, 30X, Magnesium Gluconicum Dihydricum 12X 30X, Malicum Acidum 12X, 30X, Naphthoquinone 12X, 30X, Natrum Oxalaceticum 12X, 30X, Pancreas Suis 12X, 30X, Potassium Gluconate 12X, 30X, Spleen (Suis) 12X, 30X, Stomach (Suis) 12X, 30X; Aconiticum Acidum, Cis 30X. 0.10% of Aralia Quinquefolia 3X, Potassium Gluconate 3X; Magnesium Gluconicum Dihydricum 6X, Pancreas Suis 6X, Potassium Gluconate 6X, Spleen (Suis) 6X, Stomach (Suis) 6X; Cuprum Metallicum 8X, Germanium Sesquioxide 8X, Magnesia Phosphorica 8X, Malicum Acidum 8X, Zincum Metallicum 8X; Naphthoquinone 9X; Aconiticum Acidum, Cis 12X.

INDICATIONS:

May temporarily relieve stomach discomfort, diarrhea, and fever.**

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

INDICATIONS:

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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

SPLEENEX V

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

SPLEENEX V™

INDICATIONS: May temporarily relieve stomach discomfort, diarrhea, and fever.**

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

Active Ingredients (in each drop):

2.47% of Ginkgo 6X; Aralia Quin 6X, 12X, 30X; alpha-Ketoglutaric Ac, Citricum Ac, Fumaricum Ac, Pyruvic Acid, Succinicum Acidum 8X, 12X, 30X; Cuprum Met, Zinc Met 12X; Mag Phos, Magnesium Gluconate, Malic Ac, Naphthochinonum, Natrum Oxalaceticum, Pancreas, Potassium Gluconate, Spleen, Stomach 12X, 30X; Aconiticum Acidum, Cis-, 30X. 0.10% of Aralia Quin, Potassium Gluconate 3X; Magnesium Gluconate, Pancreas, Potassium Gluconate, Spleen, Stomach 6X; Cuprum Met, Germanium Sesquioxide, Mag Phos, Malic Ac, Zinc Met 8X; Naphthochinonum 9X; Aconiticum Acidum, Cis- 12X.

Inactive Ingredients:

Demineralized water, 20% Ethanol.

LOT: XXXXXX

MFD: MM/YY 3  63113 70050 3

SPLEENEX V

aralia quinquefolia, potassium gluconate, ginkgo biloba, magnesium gluconic dihydricum, pancreas suis, spleen (suis), stomach (suis), germanium sesquioxide, cuprum metallicum, zincum metallicum, alpha-ketoglutaricum acidum, citricum acidum, fumaricum acidum, magnesia phosphorica, malicum acidum, pyruvic acid, succinicum acidum, naphthochinonum, aconiticum acidum, cis-, natrum oxalaceticum liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:44911-0539

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMERICAN GINSENG (UNII: 8W75VCV53Q) (AMERICAN GINSENG - UNII:8W75VCV53Q)	AMERICAN GINSENG	3 [hp_X] in 1 mL
POTASSIUM GLUCONATE (UNII: 12H3K5QKN9) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM GLUCONATE	3 [hp_X] in 1 mL
GINKGO (UNII: 19FUJ2C58T) (GINKGO - UNII:19FUJ2C58T)	GINKGO	6 [hp_X] in 1 mL
MAGNESIUM GLUCONATE (UNII: T42NAD2KHC) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM GLUCONATE	6 [hp_X] in 1 mL
SUS SCROFA PANCREAS (UNII: 9Y3J3362RY) (SUS SCROFA PANCREAS - UNII:9Y3J3362RY)	SUS SCROFA PANCREAS	6 [hp_X] in 1 mL
SUS SCROFA SPLEEN (UNII: 92AMN5J79Y) (SUS SCROFA SPLEEN - UNII:92AMN5J79Y)	SUS SCROFA SPLEEN	6 [hp_X] in 1 mL
SUS SCROFA STOMACH (UNII: T0920P9Z9A) (SUS SCROFA STOMACH - UNII:T0920P9Z9A)	SUS SCROFA STOMACH	6 [hp_X] in 1 mL
GERMANIUM SESQUIOXIDE (UNII: 96WE91N25T) (GERMANIUM SESQUIOXIDE - UNII:96WE91N25T)	GERMANIUM SESQUIOXIDE	8 [hp_X] in 1 mL
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	8 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	8 [hp_X] in 1 mL
OXOGLURIC ACID (UNII: 8ID597Z82X) (.ALPHA.-KETOGLUTARIC ACID - UNII:8ID597Z82X)	OXOGLURIC ACID	8 [hp_X] in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	8 [hp_X] in 1 mL
FUMARIC ACID (UNII: 88XHZ13131) (FUMARIC ACID - UNII:88XHZ13131)	FUMARIC ACID	8 [hp_X] in 1 mL
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	8 [hp_X] in 1 mL
MALIC ACID (UNII: 817L1N4CKP) (MALIC ACID - UNII:817L1N4CKP)	MALIC ACID	8 [hp_X] in 1 mL
PYRUVIC ACID (UNII: 8558G7RUTR) (PYRUVIC ACID - UNII:8558G7RUTR)	PYRUVIC ACID	8 [hp_X] in 1 mL
SUCCINIC ACID (UNII: AB6MNQ6J6L) (SUCCINIC ACID - UNII:AB6MNQ6J6L)	SUCCINIC ACID	8 [hp_X] in 1 mL
NAPHTHOQUINE (UNII: TRY8UD4E2H) (NAPHTHOQUINE - UNII:TRY8UD4E2H)	NAPHTHOQUINE	9 [hp_X] in 1 mL
ACONITIC ACID, (Z)- (UNII: OF5471ZHRR) (ACONITIC ACID, (Z)- - UNII:OF5471ZHRR)	ACONITIC ACID, (Z)-	12 [hp_X] in 1 mL
SODIUM DIETHYL OXALACETATE (UNII: 6CA025Y4FG) (DIETHYL OXALACETATE - UNII:15S56468G7)	SODIUM DIETHYL OXALACETATE	12 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:449 11-0539-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/19/2020	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0539) , api manufacture(449 11-0539) , label(449 11-0539) , pack(449 11-0539)

Revised: 3/2020

Energique, Inc.