

BIO-IMMUNE- chelidonium majus, lobelia inflata, rumex crispus, sambucus nigra, senega officinalis, spongia tosta, taraxacum officinale, myristica sebifera, sticta pulmonaria, sulphur, ustilago maidis, polyporus officinalis, candida albicans, carduus marianus, crotalus horridus, scrophularia nodosa, agaricus muscarius, bovista, secale cornutum, anas barbariae, hepatis et cordis extractum, anthracinum, arsenicum album, baptisia tinctoria, berberis vulgaris, botulinum, dysentery bacillus, gaertner bacillus (bach), 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) 3.97% of Myristica Sebifera 6X, Sticta Pulmonaria 6X, Sulphur 6X, Ustilago Maidis 6X; Candida Albicans 12X, Carduus Marianus 12X, Crotalus Horridus 12X, Scrophularia Nodosa 12X; Agaricus Muscarius 10C, Bovista 10C, Secale Cornutum 10C; Anas Barbariae, Hepatis ET Cordis Extractum 30C, Anthracinum 30C, Arsenicum Album 30C, Baptisia Tinctoria 30C, Berberis Vulgaris 30C, Botulinum 30C, Dysentery Bacillus 30C, Gaertner Bacillus (Bach) 30C, Influenzinum (2021-2022) 30C, Malandrinum 30C, Pertussinum 30C, Pneumococcinum 30C, Pyrogenium 30C, Variolinum 30C. 0.10% of Chelidonium Majus 3X, Lobelia Inflata 3X, Rumex Crispus 3X, Sambucus Nigra 3X, Senega Officinalis 3X, Spongia Tosta 3X, Taraxacum Officinale 3X; Polyporus Officinalis 8X.

INDICATIONS:

May temporarily relieve symptoms of fever, cough, swollen glands, or diarrhea.**

**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, 1 time 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:

May temporarily relieve symptoms of fever, cough, swollen glands, or diarrhea.**

**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

BIO-IMMUNE

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

BIO-IMMUNE™

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

Active Ingredients (in each drop): 3.97% of Myristica, Sticta, Sulphur, Ustilago Maidis 6X; Candida Alb, Carduus Mar, Crotalus Hor, Scrophularia Nodosa 12X; Agaricus Musc, Bovista, Secale 10C; Anas Barbariae, Anthracinum, Arsenicum Alb, Baptisia, Berberis Vulg, Botulinum, Dysentery Bacillus, Gaertner Bacillus, Influenzinum, Malandrinum, Pertussinum, Pneumococcinum, Pyrogenium, Variolinum 30C. 0.10% of Chelidonium Maj, Lobelia Inf Rumex Crisp, Sambucus Nig, Senega, Spongia, Taraxacum 3X; Polyporus Off 8X.

Inactive Ingredients: Demineralized water, 20% Ethanol.

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

LOT: XXXXXX
MFD: MM/YY



BIO-IMMUNE

chelidonium majus, lobelia inflata, rumex crispus, sambucus nigra, senega officinalis, spongia tosta, taraxacum officinale, myristica sebifera, sticta pulmonaria, sulphur, ustilago maidis, polyporus officinalis, candida albicans, carduus marianus, crotalus horridus, scrophularia nodosa, agaricus muscarius, bovista, secale cornutum, anas barbariae, hepatitis et cordis extractum, anthracinum, arsenicum album, baptisia tinctoria, berberis vulgaris, botulinum, dysentery bacillus, gaertner bacillus (bach), liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0653
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHELIDONIUM MAJUS WHOLE (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS WHOLE	3 [hp_X] in 1 mL
LOBELIA INFLATA WHOLE (UNII: 9PP1T3TC5U) (LOBELIA INFLATA - UNII:9PP1T3TC5U)	LOBELIA INFLATA WHOLE	3 [hp_X] in 1 mL
RUMEX CRISPIUS ROOT (UNII: 9N1RM2S62C) (RUMEX CRISPIUS ROOT - UNII:9N1RM2S62C)	RUMEX CRISPIUS ROOT	3 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	3 [hp_X] in 1 mL
POLYGALA SENEGA ROOT (UNII: M7T6H7D4IF) (POLYGALA SENEGA ROOT - UNII:M7T6H7D4IF)	POLYGALA SENEGA ROOT	3 [hp_X] in 1 mL
SPONGIA OFFICINALIS SKELETON, ROASTED (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	3 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	3 [hp_X] in 1 mL
VIROLA SEBIFERA RESIN (UNII: GHJ5XX5SGS) (VIROLA SEBIFERA RESIN - UNII:GHJ5XX5SGS)	VIROLA SEBIFERA RESIN	6 [hp_X] in 1 mL
LOBARIA PULMONARIA (UNII: D1YM0P5Z2T) (LOBARIA PULMONARIA - UNII:D1YM0P5Z2T)	LOBARIA PULMONARIA	6 [hp_X] in 1 mL

SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6 [hp_X] in 1 mL
USTILAGO MAYDIS (UNII: 4K7Z7K7SWG) (USTILAGO MAYDIS - UNII:4K7Z7K7SWG)	USTILAGO MAYDIS	6 [hp_X] in 1 mL
LARICIFOMES OFFICINALIS FRUITING BODY (UNII: 7IFM8431X3) (LARICIFOMES OFFICINALIS FRUITING BODY - UNII:7IFM8431X3)	LARICIFOMES OFFICINALIS FRUITING BODY	8 [hp_X] in 1 mL
CANDIDA ALBICANS (UNII: 4D7G21HDBC) (CANDIDA ALBICANS - UNII:4D7G21HDBC)	CANDIDA ALBICANS	12 [hp_X] in 1 mL
MILK THISTLE (UNII: U946SH95EE) (MILK THISTLE - UNII:U946SH95EE)	MILK THISTLE	12 [hp_X] in 1 mL
CROTALUS HORRIDUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	12 [hp_X] in 1 mL
SCROPHULARIA NODOSA WHOLE (UNII: 7H443NUB2T) (SCROPHULARIA NODOSA - UNII:7H443NUB2T)	SCROPHULARIA NODOSA WHOLE	12 [hp_X] in 1 mL
AMANITA MUSCARIA FRUITING BODY (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)	AMANITA MUSCARIA FRUITING BODY	10 [hp_C] in 1 mL
LYCOPERDON UTRIFORME FRUITING BODY (UNII: K2A74U428F) (LYCOPERDON UTRIFORME FRUITING BODY - UNII:K2A74U428F)	LYCOPERDON UTRIFORME FRUITING BODY	10 [hp_C] in 1 mL
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	10 [hp_C] in 1 mL
CAIRINA MOSCHATA HEART/LIVER AUTOLYSATE (UNII: RN2HC612GY) (CAIRINA MOSCHATA HEART/LIVER AUTOLYSATE - UNII:RN2HC612GY)	CAIRINA MOSCHATA HEART/LIVER AUTOLYSATE	30 [hp_C] in 1 mL
BACILLUS ANTHRACIS IMMUNOSERUM RABBIT (UNII: 41LZ22DD4N) (BACILLUS ANTHRACIS IMMUNOSERUM RABBIT - UNII:41LZ22DD4N)	BACILLUS ANTHRACIS IMMUNOSERUM RABBIT	30 [hp_C] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	30 [hp_C] in 1 mL
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HM5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HM5WU)	BAPTISIA TINCTORIA ROOT	30 [hp_C] in 1 mL
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	30 [hp_C] in 1 mL
CLOSTRIDIUM BOTULINUM (UNII: 0296055VE0) (CLOSTRIDIUM BOTULINUM - UNII:0296055VE0)	CLOSTRIDIUM BOTULINUM	30 [hp_C] in 1 mL
SHIGELLA DYSENTERIAE (UNII: 1EP6R5562J) (SHIGELLA DYSENTERIAE - UNII:1EP6R5562J)	SHIGELLA DYSENTERIAE	30 [hp_C] in 1 mL
SALMONELLA ENTERICA SUBSP. ENTERICA SEROVAR ENTERITIDIS (UNII: Y3V16D4PV4) (SALMONELLA ENTERICA ENTERICA SEROVAR ENTERITIDIS - UNII:Y3V16D4PV4)	SALMONELLA ENTERICA SUBSP. ENTERICA SEROVAR ENTERITIDIS	30 [hp_C] in 1 mL
INFLUENZA A VIRUS A/VICTORIA/2570/2019 IVR-215 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: WD5E5VYM2E) (INFLUENZA A A VIRUS A/VICTORIA/361/2011 IVR-165 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:W762BRG698)	INFLUENZA A VIRUS A/VICTORIA/2570/2019 IVR-215 (H1N1) ANTIGEN (FORMALDEHYDE INACTIVATED)	30 [hp_C] in 1 mL
INFLUENZA A VIRUS A/TASMANIA/503/2020 IVR-221 (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: V529EJB2CX) (INFLUENZA A A VIRUS A/TASMANIA/503/2020 IVR-221 (H3N2) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:CYN792B8TR)	INFLUENZA A VIRUS A/TASMANIA/503/2020 IVR-221 (H3N2) ANTIGEN (FORMALDEHYDE INACTIVATED)	30 [hp_C] in 1 mL
INFLUENZA B VIRUS B/WASHINGTON/02/2019 ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: VEH9U90EHX) (INFLUENZA B VIRUS B/WASHINGTON/02/2019 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:1G2CU2LIB5)	INFLUENZA B VIRUS B/WASHINGTON/02/2019 ANTIGEN (FORMALDEHYDE INACTIVATED)	30 [hp_C] in 1 mL
INFLUENZA B VIRUS B/PHUKET/3073/2013 ANTIGEN (FORMALDEHYDE INACTIVATED) (UNII: B93BQX9789) (INFLUENZA B VIRUS B/PHUKET/3073/2013 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED) - UNII:9HB0XUS9TM)	INFLUENZA B VIRUS B/PHUKET/3073/2013 ANTIGEN (FORMALDEHYDE INACTIVATED)	30 [hp_C] in 1 mL
VACCINIA VIRUS (UNII: JDS6958QAG) (VACCINIA VIRUS - UNII:JDS6958QAG)	VACCINIA VIRUS	30 [hp_C] in 1 mL
HUMAN SPUTUM, BORDETELLA PERTUSSIS INFECTED (UNII: U364V64HUN) (HUMAN SPUTUM, BORDETELLA PERTUSSIS INFECTED - UNII:U364V64HUN)	HUMAN SPUTUM, BORDETELLA PERTUSSIS INFECTED	30 [hp_C] in 1 mL
STREPTOCOCCUS PNEUMONIAE (UNII: BT6U234YR2) (STREPTOCOCCUS PNEUMONIAE - UNII:BT6U234YR2)	STREPTOCOCCUS PNEUMONIAE	30 [hp_C] in 1 mL

RANCID BEEF (UNII: 29SUH5R3HU) (RANCID BEEF - UNII:29SUH5R3HU)	RANCID BEEF	30 [hp_C] in 1 mL
VACCINIA VIRUS STRAIN NEW YORK CITY BOARD OF HEALTH LIVE ANTIGEN (UNII: 4SV59689SK) (VACCINIA VIRUS STRAIN NEW YORK CITY BOARD OF HEALTH LIVE ANTIGEN - UNII:4SV59689SK)	VACCINIA VIRUS STRAIN NEW YORK CITY BOARD OF HEALTH LIVE ANTIGEN	30 [hp_C] 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:44911-0653-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/21/2022	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0653) , api manufacture(44911-0653) , label(44911-0653) , pack(44911-0653)

Revised: 3/2022

Energique, Inc.