

**CARE AND COMFORT CREAM- aconitum napellus, arnica montana, bryonia (alba), calendula officinalis, chamomilla, colocynthis, hypericum perforatum, pulsatilla (pratensis), rhus tox, symphytum officinale cream
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

0.09% of Aconitum Napellus 12X, Arnica Montana 12X, Bryonia (Alba) 12X, Calendula Officinalis 12X, Chamomilla 12X, Colocynthis 12X, Hypericum Perforatum 12X, Pulsatilla (Pratensis) 12X, Rhus Tox 12X, Symphytum Officinale 12X.

INDICATIONS:

May temporarily relieve pain, soreness, swelling, stiffness, and symptoms of minor injuries.**

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

WARNINGS:

For external use only. If an adverse reaction occurs, discontinue use.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, 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.

Do not expose product to extreme temperatures.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Apply at least 3 times daily over the affected area.

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INACTIVE INGREDIENTS:

Water, Glycerin, Whey protein concentrate (milk), Benzyl alcohol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Aloe Vera leaf juice, Jojoba (*Simmondsia Chinensis*) Seed Oil, English Lavender (*Lavandula Angustifolia*) flower oil, Methyl Gluceth-10, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Lauryl Glucoside, Myristyl Glucoside, Polyglyceryl-6 Laurate, Sodium Gluconate, Tocopherols (soy), Salicylic Acid, Sorbic Acid, Potassium Sorbate, Sodium Benzoate, Ethanol, Citric Acid.

QUESTIONS:

Dist. by Energique, Inc.

201 Apple Blvd

Woodbine, IA 51579 **800-869-8078**

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

CARE AND

COMFORT CREAM

Net wt. 2 oz. (57 g)

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Net wt. 2 oz. (57 g)

Active Ingredients: 0.09% of Aconitum Nap, Arnica, Bryonia, Calendula, Chamomilla, Colocynthis, Hypericum, Phytolacca, Pulsatilla, Rhus Tox, Symphytum 12X.

Inactive Ingredients: Water, Glycerin, Whey protein concentrate (milk), Benzyl alcohol, Hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, Aloe vera leaf juice, Jojoba (*Simmondsia chinensis*) seed oil, English lavender (*Lavandula angustifolia*) flower oil, Methyl gluceth-10, Acrylates/C10-30 alkyl acrylate crosspolymer, Lauryl glucoside, Myristyl glucoside, Polyglyceryl-6 laurate, Sodium gluconate, Tocopherols (soy), Salicylic acid, Sorbic acid, Potassium sorbate, Sodium benzoate, Ethanol, Citric acid.

LOT: XXXXXX EXP: MM/YY

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CARE AND COMFORT CREAM

aconitum napellus, arnica montana, bryonia (alba), calendula officinalis, chamomilla, colocynthis, hypericum perforatum, pulsatilla (pratensis), rhus tox, symphytum officinale cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0639
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS WHOLE (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS WHOLE	12 [hp_X] in 1 g
ARNICA MONTANA WHOLE (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA WHOLE	12 [hp_X] in 1 g
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	12 [hp_X] in 1 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 1 g
MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA WHOLE	12 [hp_X] in 1 g
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT PULP	12 [hp_X] in 1 g
HYPERICUM PERFORATUM WHOLE (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM WHOLE	12 [hp_X] in 1 g
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	12 [hp_X] in 1 g
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	12 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	12 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	12 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
WHEY (UNII: 8617Z5FMF6)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SORBIC ACID (UNII: X045WJ989B)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
MYRISTYL GLUCOSIDE (UNII: 6AK28695LF)	
POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8W8G)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
JOJOBA OIL (UNII: 724GKU717M)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44911-0639-1	57 g in 1 TUBE; Type 0: Not a Combination Product	05/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/12/2022	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0639) , api manufacture(44911-0639) , label(44911-0639) , pack(44911-0639)

Revised: 5/2022

Energique, Inc.