

**JOINT PAIN AND STIFFNESS RELIEF- calendula officinalis, croton tiglium, natrum muriaticum, plantago major, rhus tox, sarsaparilla (smilax regelii) spray
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 spray): 0.21% of Calendula Officinalis 12X, Croton Tiglium 30X, Natrum Muriaticum 30X, Plantago Major 30X, Rhus Tox 30X, Sarsaparilla (Smilax Regelii) 30X.

INDICATIONS:

May temporarily relieve pain due to inflammation caused by but not limited to the following: sprains, minor joint inflammation, trauma.**

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

WARNINGS:

For external use only.

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 get into eyes.

Do not use if tamper evident seal is broken or missing.

SHAKE WELL

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:

Adults and children shake well and spray liberally on affected area as needed. 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.

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INACTIVE INGREDIENTS:

Aloe Vera Leaf Juice, Arnica Flower*, Caprylyl Glycol, Chaparral Leaf*, Citric Acid, Comfrey Leaf*, Dragon's Blood Croton Sap, English Lavender Buds*, Ethanol, Ionic Colloidal Silver, Lemon Balm Leaf*, PEG-8 Dimethicone, PEG-14, PEG-33, Phenoxyethanol, Poke Berries*, Poke Root*, Potassium Sorbate, Purified Water, Sodium Benzoate, Sodium Bicarbonate, Sorbic Acid, St. John's Wort Aerial Parts*, Tocopherols (soy), Vitamin C, Whey Protein Concentrate (Milk), White Willow Bark* and Yarrow Flower*.

QUESTIONS:

Dist. by Energique, Inc., 201 Apple Blvd.
Woodbine, IA 51579 **800.869.8078**

PACKAGE LABEL DISPLAY:

ENERGIQUE

SINCE 1987

HOMEOPATHIC REMEDY

JOINT PAIN

& STIFFNESS

RELIEF

Topical Spray

1 fl. oz. (30 ml)

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LOT: XXXXX



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Nat Mur 30X, Plantago 30X, Rhus Tox
30X, Sarsaparilla 30X.

Inactive Ingredients: Aloe vera leaf juice, Arnica flower*, Caprylyl glycol, Chaparral leaf*, Citric acid, Comfrey leaf*, Dragon's blood croton sap, English lavender buds*, Ethanol, Ionic colloidal silver, Lemon balm leaf*, PEG-8 dimethicone, PEG-14, PEG-33, Phenoxyethanol, Poke berries*, Poke root*, Potassium sorbate, Purified water, Sodium benzoate, Sodium bicarbonate, Sorbic acid, St. John's wort aerial parts*, Tocopherols (soy), Vitamin C, Whey protein concentrate (milk), White willow bark* and Yarrow flower*. *Extract

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 1 mL
CROTON TIGLIUM SEED (UNII: 0HK2GZK66E) (CROTON TIGLIUM SEED - UNII:0HK2GZK66E)	CROTON TIGLIUM SEED	30 [hp_X] in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	30 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	30 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 mL
SMILAX ORNATA ROOT (UNII: 2H1576D5WG) (SARSAPARILLA - UNII:2H1576D5WG)	SMLAX ORNATA ROOT	30 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
LARREA TRIDENTATA TOP (UNII: PK0TXD049P)	
COMFREY LEAF (UNII: DG4F8T839X)	
CROTON LECHLERI RESIN (UNII: GGG6W25C63)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
SILVER (UNII: 3M4G523W1G)	

MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)
PEG-8 DIMETHICONE (UNII: GIA7T764OD)
POLYETHYLENE GLYCOL 700 (UNII: 762678AC5R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SORBIC ACID (UNII: X045WJ989B)
PHYTOLACCA AMERICANA FRUIT (UNII: WE63661499)
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0K00R)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
WHEY (UNII: 8617Z5FMF6)
SALIX ALBA BARK (UNII: 205MXS71H7)
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)
ALCOHOL (UNII: 3K9958V90M)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:449 11-0304-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/18/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/18/2015	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(449 11-0304) , api manufacture(449 11-0304) , label(449 11-0304) , pack(449 11-0304)